Thesis: Measurement of Patient Anxiety in MRI - Comparing VR Simulation to a Questionnaire

Helen Figg
Student Id: figg85053051

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Supervisor: Dr Christoph Bartneck

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Table 0.1: Abbreviations

BP	Blood Pressure
BPD	Diastolic Blood Pressure
BPS	Systolic Blood Pressure
EDA	Electrodermal Analysis
GSR	Galvanic Skin Response
HMD	Head Mounted Display
HR	Heart Rate
MRI	Magnetic Resonance Imaging
SCL	Skin Conductance Level
SCR	Skin Conductivity Response
STAI	State Trait Anxiety Inventory
VR	Virtual Reality
Vxxxx	VR Scan Experience..
Mxxxx	MRI Scan Experience.. (real)
xxxxB	... Before measure
xxxxD	... During measure
xxxxA	... After measure
VxxxA	xxx anxiety measure (e.g. HR)

0.1 Abstract

Magnetic resonance imaging (MRI) is a widely used, expensive procedure to obtain detailed images of the human body for diagnosis of many medical conditions. The quality of the images is significantly affected by movement of the patient, with some images even being rendered unsuitable for use. This is important because of the substantial cost involved in use of the scanner and clinical support of the patient. To minimize the risk of anxious movement causing a failed scan, some patients are sedated using medicine, however it may be that this is sometimes unnecessary. Only those who undergo an MRI without sedation first, will know if sedation was required, incurring significant cost.

This master thesis project investigates a new low-cost technology option, the use of a fully immersive virtual reality (VR) simulation of the medical procedure itself as a means to estimate patient response. A prototype is developed and tested in a user study, first in the lab with volunteers, and then with MRI hospital staff on site. Once refined, the virtual reality simulation is offered to patients immediately prior to their scheduled MRI scan. Patient anxiety levels are recorded throughout the VR and MRI procedure to gain a clearer understanding of stress profiles of individual patients. The main question is whether VR is useful in predicting anxiety of patients during MRI.

Results showed that there was a strong correlation between patient anxiety in VR and in MRI but also, if VR were removed a strong correlation existed between before MRI and during MRI. Both significantly predicted average anxiety during MRI, with VR accounting for 71.4% of anxiety during MRI of which 58.8% could be predicted by using anxiety before any scan. The main effect of exposure showed that there was no statistically significant difference in anxiety level between those who had VR and those who did not. The main effect of stage showed there was no statistically significant difference between anxiety level at the different time points of the scan. Overall anxiety level data showed no statistically significant interaction.

0.2 Acknowledgements

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Finally I dedicate this thesis to my beloved father Frederick and thank my heavenly Father for getting me through.

Chapter 1

Introduction

MRI diagnostic imaging relies on a patient remaining motionless for a significant length of time. This can be very demanding on an anxious patient and if movement renders the image useless,repeating the procedure may be required at huge expense to all involved.

The MRI scan procedure uses magnetic fields and radio waves to take magnetic resonance images. Providing medical guidelines are followed, there is no known risk involved in exposure to these waves, however because the procedure is noisy and requires the patient to be placed in a small, tight enclosure, patients of all ages can find this a traumatic experience. In order to obtain clear medical images, the patient needs to be still during the scanning process, with session length dependent on what the MRI technician sees, usually between fifteen to ninety minutes with an average of forty five minutes. If the patient moves due to anxiety, pain or discomfort, the images can lose their diagnostic value through blurring or generation of artifacts, with the worst cases requiring termination of the scheduled scan. 'These missed or increasingly difficult scans have financial implications as valuable staff and equipment time is lost' (Munn & Jordan, 2011).

For patients deemed likely to move, the administration of a general anesthetic (GA) will ensure that the patient remains still, thus giving the maximum potential for clear diagnostic images. However, the GA process itself is the last resort because it is detrimental on many levels (de Bie et al., 2010) and the financial cost of a GA MRI scan is substantially higher with an additional clinical team required to support the procedure plus the additional time the scanner is idle. In Christchurch Hospital, NZ, five extra staff are required for GA MRI and scanner time costs 2753 NZD per hour[1]. The temporal cost for others dependent on these resources (both GA and MRI) result in enforcing longer wait times on other patients and subsequent diagnosis of their medical conditions. Taking the GA procedure out of the operating theatre (working remotely) increases risk of further incident. This is all in addition to the increase in medical risk of undertaking GA itself for the patient, so where possible, use of GA is to be avoided. Adult recipients are offered the option of sedation, ranging from the minimum level (anxiolysis) where the patient remains conscious and responsive through to full GA. (Bahn & Holt, 2005). Only those who undergo an MRI without sedation first will know if they require sedation, but this is costly.

This thesis looks at a new, affordable technology option to simulate the experience in virtual reality (VR) as a potential method of predicting the likelihood of anxiety and subsequently whether GA is required. The MRI procedure investigated was a brain scan procedure. If this can be used to successfully predict the reaction of the patient in the scanner it could be useful to clinical staff as another tool in

[1]Based on MRI Head quote from `http://www.christchurchradiology.co.nz/assets/files/QMCFEE004R-CRG-MRI-Fee-Synopsis.pdf` accurate as of 1 April 2016

assessing the need for sedation. VR is used currently in areas of health for medical training and exposure therapy but very seldom involving the patient experience which remains novel in the field. This opens the way to further research of patient experience and their use of VR.

1.1 Research Questions

Hospital staff posed the question: 'Is VR useful in predicting anxiety of patients during MRI?'

To address, this thesis aims to answer three research questions:

- Does exposure have an influence on anxiety?
- Does stage have an influence on anxiety?
- Is there an interaction between stage and exposure on anxiety?

The terms 'exposure', 'stage' and 'anxiety' are used to mean; 'exposure to a virtual reality simulation of an MRI brain scan procedure', 'time point within the patient experience of an MRI brain scan procedure (real or virtual)' and 'the anxiety level of the patient during the real MRI brain scan' respectively.

During completion of the thesis, two further questions were raised

- What is the correlation between anxiety before MRI and during MRI? and
- What is the correlation between anxiety during VR and during MRI?

1.2 Contribution

The main contributions of this thesis are:

- A novel intervention[2] for MRI offering a virtual reality simulation of an MRI brain scan using a mobile, low cost head mounted display (HMD - Samsung Gear VR) with accompanied sound, vibration, restriction of movement and body positioning. This combination enables the user to experience a sensory simulation prior to their medical procedure, within the same hospital environment.
- A user experiment researching the effect of patients experiencing the virtual reality simulation of an MRI brain scan prior to the medical procedure.
- An extension of the user experiment to compare those patient users in the experimental group against control patients who did not have any intervention prior to their MRI brain scan medical procedure.
- A user study to assess the fitness of purpose of the designed VR simulation within a medical setting.

[2]In health, intervention can be defined as 'The act of intervening, interfering or interceding with the intent of modifying the outcome' http://www.medicinenet.com/script/main/art.asp? articlekey=34214 accurate as at 14/8/2017'.

- A proof of concept of offering an effective mobile solution for patients to try out in their own home to build familiarity with the experience.
- A proof of concept of using VR to simulate a medical procedure.

1.3 Thesis Structure

The next chapter gives a survey of related work (2). Iterative design and usability testing of the prototype is outlined in chapter three (3) and discussed in more detail in chapter four (4) which covers pilot runs in the lab and hospital environments. The resultant VR system created is summarised in Chapter five (5). Chapter six presents the user experiment in detail (6) and chapter seven, statistical analysis of the results (7). The findings are discussed in chapter eight where limitations of the study are introduced and recommendations given (8). Finally, chapter nine draws conclusions and highlights further research questions raised in the course of doing this thesis (9). Included in this chapter for reference, is exploratory analysis which may prompt future work via desk review (i.e. using the data made available by this user experiment). Appendices contain supplementary information and study forms.

1.4 Ethics Approval (ref No. HEC 201632)

Approval from the Human Ethics Committee (HEC) at the University of Canterbury (UC) was granted (ref. no. HEC 201632), subject to approval from both the Director of the MRI Unit at CDHB and Consultant Radiologist at University of Otago. This decision was accepted as satisfactory by the Health Board's ethical committee with no further action required. UC HEC classed the experimental study as high risk. The Maori director of Research at UC concurred that he did not require further consideration. For details see Appendix B.

Chapter 2

Background

This thesis aims to investigate whether a virtual reality simulation of an MRI brain scan can assist with detecting patient anxiety in the real scan. This chapter surveys related work done on the topic. The first section (Section 2.1) looks at the patient experience of MRI and why it causes a problem that can require sedation, including why treating with sedation is not desirable. The second section (Section 2.2) outlines alternative interventions which help to overcome the need for sedation. The third (Section 2.3) considers virtual reality as a new option for intervention. The fourth (Section 2.4) looks at similar VR applications which have been developed to date and their limitations. Lastly, the fifth (Section 2.5) considers how anxiety can be measured in the user study.

2.1 Patient Experience of the MRI Scan

One of the consequences of patient anxiety in MRI is the high probability that the patient will terminate the procedure early. Anxious patient reactions go from feeling a little nervous through to a compulsive desire to escape (Munn & Jordan, 2013a). Patients have reported feelings of claustrophobia. Claustrophobia can be classified as the fear of enclosed spaces or being trapped, restricted or suffocated. Because it encloses the head, the brain scan is considered the most distressful for an anxious patient (Munn & Jordan, 2013a).

In 2015, the first systemic research selected eighteen studies of large sample size looking at the evidence for the prevalence of claustrophobic reactions during MRI (Munn, Moola, Lisy, Riitano, & Murphy, 2015). This was measured as refusal to go into or complete the MRI scan process. Across these studies, up to five percent of the population reported claustrophobia. Taking an average, Munn and his fellow researchers concluded one to two out of every one hundred patients will show claustrophobic reactions (noticed to be more prevalent in females and participants of senior years). Numbers of those who experienced claustrophobia and still went on to complete the scan have not been reported.

Unsuccessful scans are not only related to claustrophobia; four to twenty percent of all patients refuse to undergo the MRI session or terminate early. (Garcia-Palacios, Hoffman, Richards, Seibel, & Sharar, 2007). Studies have shown pain correlates to anxiety during the scan and early termination. (Katz, Wilson, & Frazer, 1994; Enders et al., 2011) along with other factors including the unknown, loud noise, fear of diagnosis, lying still and duration. While it has been argued by Munn, that some studies reviewed were too small to gain a statistically significant result, it is indicative of a trend of consistent findings. An unfinished scan is detrimental to the patient as it may delay potentially urgent medical care and may raise their anxiety in future scans. Among patients interviewed one month after their scan, ten percent

reported feeling more nervous in confined spaces.(Munn & Jordan, 2012). Anxiety can lead to repeating the MRI scan sequence or at worst cancellation of the procedure with valuable time, manpower and patient opportunity lost.

The only way certain to avoid an unsuccessful scan is with full sedation (also known as general anaesthetic or GA), but as mentioned in the previous chapter this is costly and to be avoided. The problems of claustrophobia and anxiety can be totally resolved by sedation or full analgesia (GA) (Esen, Calim, & Kadioglu, 2017). However, the risks of sedation vary widely from the common temporary drowsiness, nausea, impaired vision and judgment through to the rare occurrence of breathing difficulties or fatality. The majority of interventions seek to avoid sedation or full analgesia which when taken out of the operating theatre have shown worse outcomes for the patient where risk has been introduced due to lack of both equipment found in the operating room and compatibility of operating room equipment with the MRI environment. (Marshall, Martin, Downie, & Malisza, 2007). In order to avoid risk and cost, it is prudent to avoid General Anesthetic (GA) if at all possible (de Bie et al., 2010). To avoid unsuccessful scans or sedation, many alternative interventions have been researched.

2.2 Alternative Interventions to Sedation

In 2011 the first systematic review was published which looked at interventions to lower anxiety and distress in magnetic resonance (MR) imaging. Twenty one studies were reviewed, fourteen being random controlled trials (RCT) and the other seven, cohort studies with a control group (Munn & Jordan, 2011).

Apart from sedation, successful interventions include additional information (verbal or written) coupled with emotional support, audio/visual distraction, cognitive behavioural therapy (as part of an anxiety reduction protocol) and quieter machinery. Mixed results were gained from additional information regarding procedure. Open bore MRI designs resulted in less patient anxiety but poorer quality images and longer scan times. Other interventions did not yield satisfactory results or were excluded from review after critical appraisal. These included dedicated low field scanner, prism glasses, lighting levels, movement of air/fans, installation of panic buttons and having company attend. Munn recommends larger rigorously controlled trials in many of the studies. (Munn & Jordan, 2012, 2013b, 2014; Munn, Pearson, et al., 2015).

MRI team provision of reassurance, care and connection with the patient has been shown to be effective in reducing patient anxiety, fear, claustrophobia and the need for sedation (Munn, Pearson, et al., 2015). Researchers agree that the two barriers to overcome are: level of anxiety/distress and participant movement. Many interventions, including use of a mock scanner (Nora M et al., 2009) and (de Bie et al., 2010), demand significant investment of time to be of optimal success. As staff and patient time is at a premium, there is room for research into an alternative approach.

2.3 Simulation of an Environment in Virtual Reality.

Virtual Reality (VR) can be defined as an immersive experience, where the user is free to move about the environment as they see fit. To achieve this freedom of movement, the scene is modelled as a three dimensional object on a computer, rather than being a collection of photographs or videos. Mueller's work (Mueller et al., 2012) has introduced a framework for including immersive virtual experiences and led to an increase in research interest in VR

Gaggioli introduced the term 'interreality (IR)' for a technological paradigm linking virtual and real worlds together using virtual scenarios (Gaggioli et al., 2014). It combines the use of a virtual experience guided by a therapist with real-time monitoring and support using advanced technologies such as wearable bio-sensors, virtual worlds and smart-phones), to enable VR to directly address problems experienced in the real world and ultimately decrease the level of chronic 'trait' stress.

In conclusion, his research gave initial evidence that a technology-enhanced interreality protocol provides better outcomes that the traditional gold standard of Cognitive Behaviour Therapy (CBT). Interreality was able to significantly reduce persistent trait anxiety, unlike CBT. A future research goal is to investigate the benefit of reducing anxiety and stress through VR feedback of experience and bio-sensors. From these findings, VR has a direct influence on the way events are perceived and holds promise for a new approach to the patient experience for MRI.

Many studies referred to by Gaggioli found VR effective in the treatment of post traumatic stress disorder (PTSD) He found PTSD symptoms could be triggered by day-to-day work related events in nurses and VR was especially useful where traditional methods were not suitable.

Use of VR distraction for pain relief in wound care is very real and the benefits currently used to improve patient outcome in the wild. (Garcia-Palacios et al., 2007; Hoffman, Richards, Coda, Richards, & Sharar, 2003)

Virtual Reality has the ability to create a sense of presence in a dangerous simulated world, inducing a level of situational anxiety. This has been successful in situations of high cost both financially and in terms of human risk if the user is not ready (i.e. flight simulation used for pilot training) (Rothbaum, Hodges, Watson, Kessler, & Opdyke, 1996; Rothbaum, Hodges, Smith, Lee, & Price, 2000; Wiederhold et al., 2002). There are similarities here with the high cost MRI environment and patient readiness even where MRI scans are routine they can still bring on anxiety.

Similarly in personal therapy, VR has enabled study of user reactions when exposed to phobias in a safe environment. Literature from over 90 studies of virtual reality exposure treatment VRET have been reviewed at a meta-analysis level led by Parsons, Powers and Bush (Parsons & Rizzo, 2008; Powers & Emmelkamp, 2008; Bush, 2008). Meta-analysis supports the efficacy of VRET, suitable for patients too anxious for real-life exposure and the potential to research a broader application into the clinical arena where this can be directly applied to the MRI environment.

Weiderhold found a number of studies have shown that combining VR with traditional therapies leads to more efficient and successful treatment outcomes. "Data from fMRI studies is proving increasingly relevant in confirming on a neurological level what has been observed with self-report and physiological data." (Wiederhold & Wiederhold, 2008). Further research is required within age groups in both distraction and VR distraction studies during an MRI.

To assess the effect of VR experience on a patient, the most commonly used subjective measures are simple cognitive testing and self-report questionnaire. Common physiological measures include skin conductance, heart rate, peripheral skin temperature and respiration rate.

2.4 Existing VR Applications

There are some existing virtual reality applications which reference this MRI simulation. Siemens have released an android application[1] available via the Google App Play store which provides a simulation

[1] `https://play.google.com/store/apps/details?id=air.mriandroid` accurate as at 12 July 2016.

of what one can expect when in the MRI experience by moving a hand-held device in an arc where the scanner would be. There is also a child friendly version.
An alternative, Cinemavision provides distraction for the patient in a similar way to watching a video while lying in the MRI scanner. Using a bespoke integrated MRI compatible goggle and headphone unit it is described 'like watching a 62" TV screen' from 1.7 metres away. DVDs and broadcast TV can be played alongside two-way communication with MRI staff. Marketing is particularly aimed at parents to enable children to undergo their scan without GA or sedation. The negative is the proprietary solution is too expensive for most hospitals to use at a cost of 54,000 USD for the unit. [2].

The most relevant to this research found, was a first person MRI experience,[3] which if it detects patient head movement pops up a message that the scan will abort. To date, there has been no clinical evaluation or formal user study. The intention is to work from this concept under controlled conditions in a medical hospital environment.

2.4.1 Most recent developments

Manufacturers are starting to use VR to show what their product does [4] Building on top of 360degree video is a VR MRI Scan demonstration released in February 2017 by King's Hospital (London, UK). This is complimented by the 'My MRI at King's' app recently released for free on Google playstore for use by NHS UK hospitals aimed at paediatric patients [5].

Currently there a lack of scholarly literature on clinical trial of VR for patient experience. Initial demo videos show it is an area actively growing in interest and one ready for the first step of moving into the hospital for tests.

2.5 How to Measure Anxiety

By its very nature, affective neuroscience is very difficult to measure due to the emotionally complex lives we lead (Gardhouse & Anderson, 2012). Anxiety in undertaking the MRI scan can be caused from a number of elements of fear, such as: enclosed spaces, the unknown, being hurt and the resulting diagnosis (Katz et al., 1994). Previous bad experiences which have been heard from family or friends can add to this mixture of fears, and many patients experience situational anxiety. A number of academic papers use the self-reported Spielberger STAI State Trait Anxiety Inventory (Spielberger, 1983) to measure the presence and severity of current symptoms of anxiety (state) and a generalized propensity to be anxious (trait).

When compared with the above, a short version of the self-report questionnaire, State-Trait Anxiety Inventory (STAI Y-6) reported favourable state anxiety results (Marteau & Bekker, 1992). This fits the requirement within a clinical procedure where optimum time and patient flow are a high priority. Two short form STAI questionnaires are in commonly used, Tluczek points to the use of Marteau's six item as opposed to Chlan's (Tluczek, Henriques, & Brown, 2009).

Some other measures used include: MRI Screen, The Fear Survey Schedule (Geer, 1965) and the Hospital Anxiety and Depression Scale (HADS). These were investigated and found to be less relevant for the target audience.

[2] accurate as at 6 Sept 2017
[3] written in Unity `https://www.youtube.com/watch?v=mQHWkRvo37Q` accurate as at 6 Sept 2017
[4] `https://www.youtube.com/watch?v=Gsq0IRTU9a0` accurate as of 9 Sept 2017.
[5] `https://play.google.com/store/apps/details?id=air.mriandroid` accurate as at 9 Sept 2017

A history of research has given a number of terms relating to the change of electrical characteristics of the skin. These have been standardised to electrodermal activity (EDA). Physiological measures include skin conductance level as a useful measure which only relates to the non-sympathetic nervous system, steering clear of the sympathetic emotional/arousal elements (Bishop & Forster, 2012). EDA is usually measured at the palmer sites, in the centre of the hands or feet because the density of the sweat glands is highest here (>2000/cm squared) (Setz et al., 2010). Thus, skin conductance appears to be predictive of stress, whereas heart rate or heart rate variability also includes arousal. (Setz et al., 2010).

Physiological measures need back up of a second or third measure with which to compare. Looking further, the Spanish Ministry of Defence funded a study of wearable biomedical devices including a bespoke sensorised glove and arm-strap to give real-time galvanic skin response feedback monitoring stress levels. Other products available to measure skin response are glove-like devices and wristbands. All need to be linked to a skin impedance monitoring device. The study concluded that when recorded with biomedical systems, results suggest cardiac and respiration activity offer better bio-markers for stress assessment than speech, skin response or skin temperature. (Seoane et al., 2014). The latest products available are gloves with textrodes (electrodes made from textiles) integrated into the item. Conversely, latter study appears to advocate the use of an alternative over skin conductance. Therefore it may be necessary to consider the use of both skin conductance and heart rate/variability (HR/HRV) sensors. (Shastri et al., 2001).

2.5.1 Measuring Anxiety During an MRI

Munn found across the 29 studies in his thesis (MUNN, 2013), there were three approaches used to measure anxiety: observation, self-report and physiological. Of this, only two used the physiological methods which were serum cortisol levels, pulse and blood pressure. Recognising this gap, a recently published paper uses heart rate (HR) and blood pressure (BP) to measure the level of patient anxiety while undergoing an MRI scan (van Minde, Klaming, & Weda, 2014). It pinpoints the very start of the scan and the point where the loud scanning noise initiates as the points where anxiety peaks, which anecdotally matches the experience of the MRI team working at Christchurch hospital.

From this we can use the detail to look at the objective measures reached by the participants at these points. That said, the most valuable for this study will be the maximum values reached during the experience, both in VR and MRI.

Consideration was given to the use of the Hospital Anxiety and Depression Scale sourced from National Institute for Health and Care Excellence (Julian, 2011) which has 7 questions for anxiety. These were found to be less suitable than the STAI when assessing each question against those in the STAI Y-6. This was because they they did not relate to the situational anxiety an MRI scan created but focused more towards trait and state of mind.

Heart rate variability (HRV) was compared to the use of heart rate(HR). HRV although a good measure for recognition of anxiety, required a duration of at least two minutes whereas reading HR using a blood pressure (BP) monitor gave results as soon as BP was detected, was available and already used in situ. Also HR was measured by the IOM grapher, which provided an alternative if backup was required.

A questionnaire has recently been developed specifically to measure patient anxiety during the MRI procedure (Ahlander, AArestedt, Engvall, Maret, & Ericsson, 2016). This paper mentions 10-15 participants per item are recommended by Pert (Pett, 2003) giving 60-90 on the previous STAI Y-6 questionnaire. Others recommend 100-1000 participants (MacCallum, Widaman, Zhang, & Hong, 1999).

It was decided better at this time for this thesis study to remain with using the STAI Y-6 questionnaire, based on the standard STAI which was mature in the industry. The MRI-AQ paper also gave insights into the interpretation of the STAI Y-6 matrix from that mentioned in similarity to the STAI, the most commonly used questionnaire to assess anxiety in MRI (Ahlander et al., 2016). Bringing together the use of physiological and self-report data Munn refers to deploying the approach of action research where both quantitative and qualitative data gathering are appropriate for medical imaging (Munn & Jordan, 2013a).

A recent study has questioned the evidence of fMRI findings with the observation of a dead salmon showing brain activity. Counter-arguments abound, leaving a subject still under active discussion, highlighting the immaturity of clinical evidence relating to the neurological impacts of VR use outside laboratory conditions. A considered opinion on the topic of fMRI for students and scholars alike can be found in Markett's book, Neuroeconomics (Markett, 2016).

2.6 Conclusion

Assessing how patient anxiety can be relieved, there are a number of non-sedative interventions a health professional working on preparation for MRI can engage in order to avoid the risk and cost of sedation or analgesia. Local hospital procedures and constraints create a framework within which these need to fit and be determinant to what is selected for a given medical facility. Currently one of these interventions involves virtual reality.

The onset of VR has introduced VR distraction as an intervention which may be used inside and outside of the MRI room. Relatively established outside of MRI, a different use of VR, exposure therapy (VRET) for phobia; subjects the patient to the environment causing anxiety, with a prior understanding of how the patient may react. Within the MRI suite, there is an opportunity to build on this research area, not only for VRET but also for patient experience in which the patient, as user, experiences what is to come.

VR is a field which remains largely unexplored in the medical environment for patient experience . The virtual world introduces a novel approach for experiencing an unknown situation in a safe environment and is a natural fit for those naive to MRI. Practical use of VR for tackling real world problems is being enabled by the growing availability of consumer products now coming onto the market. VR use by patients in health care is a fresh area opening up for research addressed by this thesis. The next challenge to consider at this point is how to measure patient anxiety.

Previous studies show consistency in the presence of situational anxiety for many in relation to the MRI experience. Skin conductance level (SCL), introduces the use of a physiological measure for this anxiety which is from a non-sympathetic source, (i.e. not affected by emotion). Therefore the novel use of skin conductance as a measurement for anxiety experienced during MRI is proposed as a physiological measure.

Use of one measure ideally needs to be backed up by another, both quantitatively and qualitatively. Heart rate was the proposed complimentary physiological measure plus the self-report industry STAI Y-6 questionnaire. Qualitative data was harvested using structured interview questions. Action research, an approach using both self-report and physiological measures was selected as it meets the needs of the MRI operational team and the University of Canterbury exploratory use of virtual reality in a medical environment.

This thesis explores the use of virtual reality simulation of a medical procedure with review by quantitative and qualitative methods. The intent is the results may then be used to direct business process

in managing better patient health outcomes. If proven successful, hospitals may look toward subsequent implementation.

Chapter 3

Development

This chapter presents the design process which was undertaken to create the prototype. A system was developed to replicate the patient experience of an MRI brain scan in a virtual environment. The brain scan was selected because it is one of the most distressful for an anxious patient. Design started with requirements gathering. This led onto ideation and development of a prototype worthy to take into the hospital environment for further design consideration.

Throughout the whole development phase from initial design to completion of the patient pilot, continuous improvement was executed through iterative cycles of system refinement of both the VR application and associated physical factors.

The requirements demanded a lightweight portable solution which could be executed in the hospital for in-patients but mobile enough to consider future development to take home as an alternative preparation for the medical procedure. After consideration of alternative head mounted displays, the Samsung Gear VR was selected as it needed only a mobile phone for display. The researcher designed a bespoke system and oversaw development of the VR application written in Unity using a 3D model of the MRI scanner and head coil from manufacturer, Siemens and photographs taken from a similar facility while it was in the installation phase.

The final stage of the pilot, with three patient volunteers uncovered three significant findings for the resulting user experiment.

1. The use of skin conductance sensors in the scanner room was removed.
2. This was replaced with measurement pre and post experience using the skin conductance sensors on fingers.
3. An additional piece of hospital equipment for pre and post measurement, a blood pressure monitor was introduced to record heart rate and blood pressure.

3.1 Design Process

Initially this was aimed at children up to 8 years old, the category causing a particular movement issue for the imaging staff. Play therapy had been proven over the last 18 months to be successful in preparing for MRI scans in the care of children at Christchurch Hospital, but this was a lengthy and costly process which had fifteen patients through to date. For ethical reasons, it was decided to switch focus of the study to healthy adult patients booked for an MRI brain scan.

3.1.1 Requirement Gathering

The first requirement was to experience an MRI brain scan. The researcher and developer were given a short diagnostic scan. The brief was simply, replicate this in VR with as many senses as practical.

Personal experience yielded information on two levels, first the practical look and feel required of the procedure we were replicating and second, the opportunity to record thoughts and emotions which are prompted by the medical procedure.

A second observational study took place. The researcher stayed in situ at the hospital for a few days while a number of patients experienced their MRI scan. Included were a general anaesthetic sedation (GA), a child after play therapy and adults of various ages. This brought a sharp focus on the time critical use of all resources and the very dynamic flow of patients through the MRI suite. Key resources were not just the scanner but medical and administrative staff from various departments and the patients themselves. All were working to achieve maximum efficiency at minimum cost. Thus setting the margins and constraints within which the experiment was to run and a hospital protocol defining this to be written.

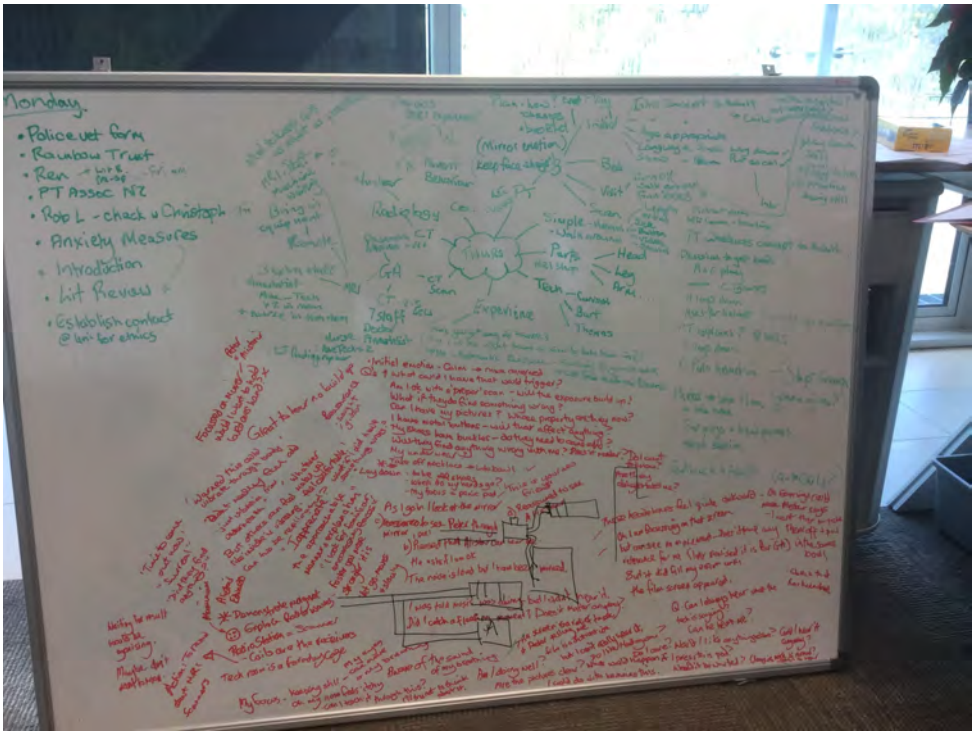


Figure 3.1: First hand user experience of MRI brain scan - thoughts and emotions

The whiteboard shown in 3.1 gives an initial dump of the emotions and thoughts the researcher felt during the scan. This was gathered as a brainstorm session on return to the Lab following the MRI scan. Structural information and things to consider in design were written in green. Thoughts and emotions conjured up by the experience from the anxious user perspective were written in red.

A sample from the board were:

GREEN:

- GA must be kept as short as possible; working remote from operating theatre with five extra staff and equipment in MRI room

- Are you in the right frame of mind to take this in? Warning: if you do have these conditions DO NOT have MRI.
- Note parent behaviour, keep face straight, use simple language and mirror patient's emotion.

  RED:

- Initial emotion, calm then more concerned, focused on the mirror.
- I'm reassured to see MRI tech through the mirror. I can hear them, Can they hear me?
- Now my focus shifted to the panic pod 'this is your new friend' the MRI tech said.
- Will they find anything wrong with me? Does it matter? Do I want to know?
- These headphones feel quite awkward. My focus, keeping still, oh my nose feels itchy.
- I can't quite see the coil, it's almost touching my nose and out of focus. My eyes can move and aware of the sound of my breathing.
- These headphones feel quite awkward. My focus, keeping still, oh.. my nose feels itchy.

3.1.2 Ideation

At a high level the process was defined (reading figure 3.2 left to right.)
MRI reception - the patient presents for their appointment.
Meet the MRI technician - who asks if they would like *music* (or *video* for children).
Going into the MRI room - have all metal objects been removed?
Ask questions - is there anything the patient wants to know?
Walk around the MRI room - take in your surroundings, the MRI makes a constant chirp sound.
What is an MRI machine - what is going to happen to me?
Get onto the bed - and lay back into position, need to be comfortable.
Tech will fit the equipment - need this coil over your head for the pictures to be taken. Now we begin...
Going in ... sliding head-first, back into the bore.
Scanning ... the loud noise will come in short bursts when you must lie perfectly still to get good images.
Coming out ... all finished now.
Going home ... thank you, it's all over, well done.

A storyboard was drafted of the process being replicated. The need for simplicity and practicality reduced initial design to only the far right column, from 'Get on to the bed' to 'Coming out'.

Reading the diagram from left to right in figure 3.3a, it has three boxes; 'Fitting the equipment', 'Going in' and 'Coming out'. *Fitting the equipment* has the bullet points: Coil; earplugs; headphones; blanket and panic pod. *Going in* has the bullet points: What can you see? Look around from your position; Staying still; I can hear you; I can see you; Can you see me? *Scanning* has bullet points: The noise; Duration; What if i move?; Staying still; Vibrations - simulate.

All through the patient's attention is focused on the mirror where they can see the MRI tech asking Are you OK? Figure 3.3b has two boxes; 'Your MRI Experience' and 'Coming Out'. *Your MRI Experience* has the bullet points: Select time slots; Go...; Squeeze pod - stop; repeat - you control / Auto. *Coming Out* has bullet points: Slide out; Get down from bed; Put back metal items; Greet parents.

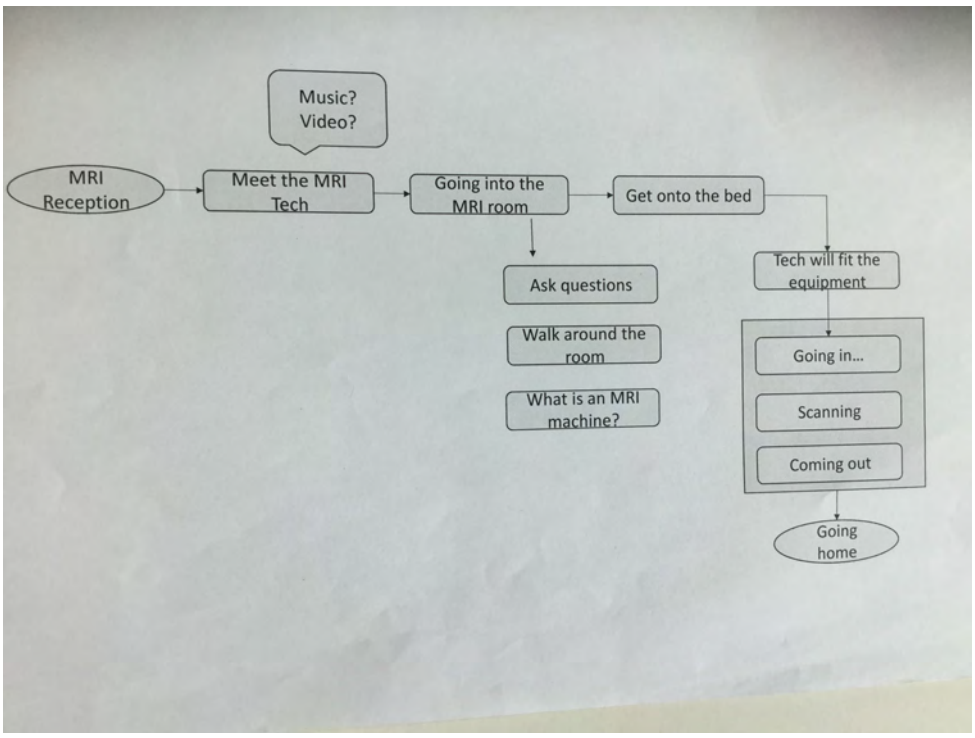
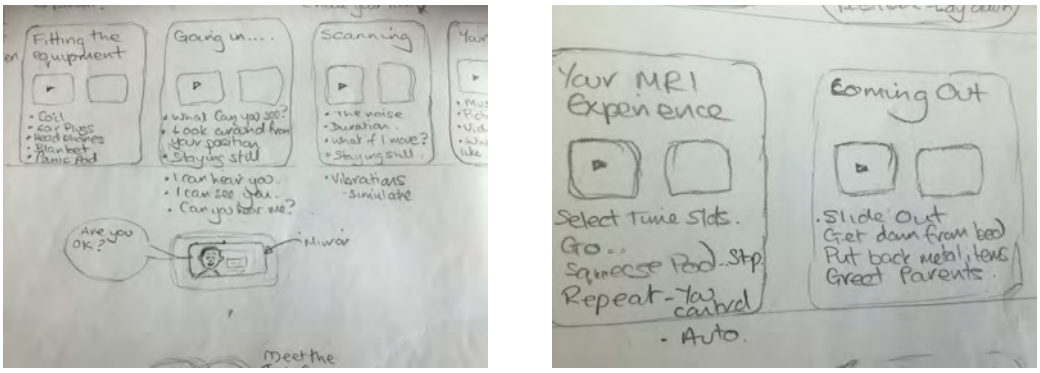


Figure 3.2: Simple process flow



(a) Going in

(b) Coming out

Figure 3.3: Storyboard of flow

3.2 Prototype

First a visual prototype was developed by a third party developer working with the MRI specialist and I. They created the initial environment using the manufacturer's 3D models of the scanner and head coil (a.k.a. helmet or head brace) and some photo shoots of a similar facility. As the researcher, I worked closely with the developer defining how the user explored and interacted with their virtual and physical surroundings during the simulation.

Visuals were developed first. Recent study on presence in VR has indicated that a self-avatar is better than no avatar. However, if the avatar is to move, it's movements need to be in synchronisation with the user's own body, otherwise that sense of presence is lost. So a static avatar is preferable in cases where full embodiment is not possible. (Steed et al., 2016). For this reason, a static avatar was used.

For the brain scan, after laying back, the helmet (or head coil) gave an anchor point for the user. It needed to give the sensation that the helmet was really close, blurred and almost touching their nose.

Movement of the virtual camera was along the horizontal plane, taking the user back in and then releasing out of the bore.

Onto the visuals were layered the constant background chirp sound of the scanner; then the bed going in, three scanning sequences and the bed coming out. Finally the voice-over of the MRI technician was layered on top, talking the patient through the scan procedure as naturally as possible.

Various interactions of visual and audio cues were designed and tested to ensure the best outcome for replication of patient user experience.

3.2.1 Development of the VR Prototype

Initial development by the third party was in Unity 5.3, with 360 degree video for familiarisation and packaged onto Google cardboard for proof of concept. A Samsung Galaxy S6 Edge phone was used throughout (with a number of enclosures). It was important that the MRI room environment be created as a 3D model so that the user may explore for themselves. This made a point of difference with the 360degree video in place at the time on Siemens android application[1]. A 3D model was sourced from Siemens for the MRI scanner and the head coil. To keep motion sickness to a minimum the user remained seated or laying down. The user laid down on their back to signal they were ready to start. After a seven second time delay (to allow for the head brace to be fitted manually), the user sees the head brace and mirror close up and is transported back into the bore of the scanner with the accompanying audio scanning sequences.

The next task was to create a realistic model of the MRI environment illustrated in figures 3.4 and 3.5. An outline brief is given in Appendix C.

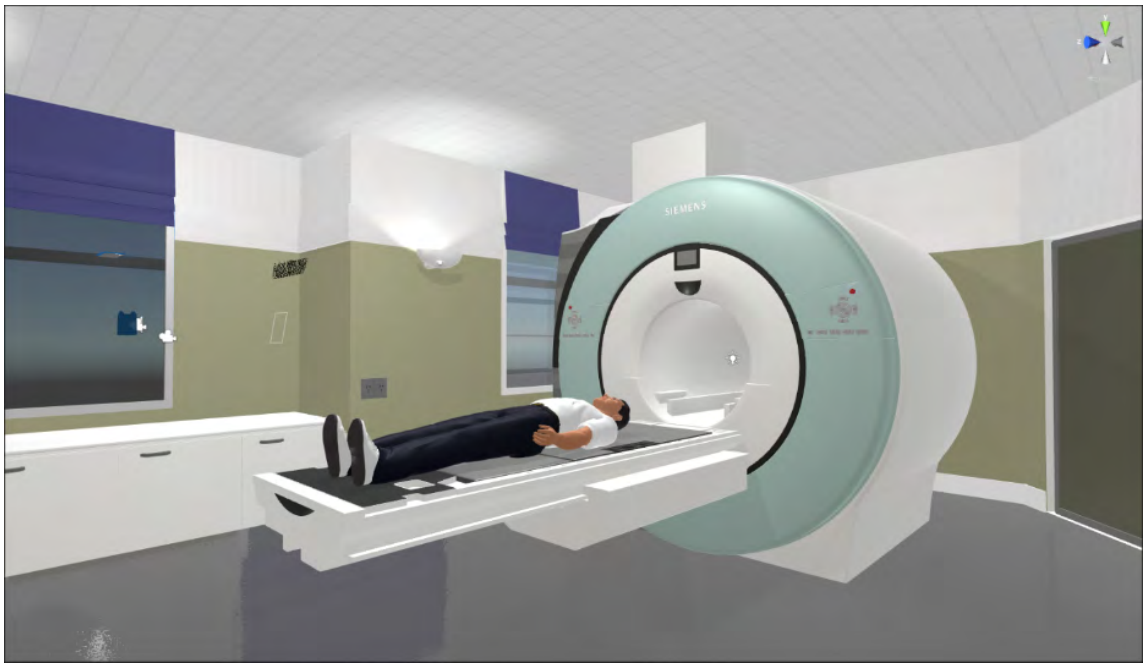


Figure 3.4: Prototype 3D model of MRI scanner

3.2.2 Prototype Summary

A system was developed to replicate the patient experience of an MRI brain scan in a virtual environment.

[1] `https://play.google.com/store/apps/details?id=air.mriandroid` accurate as of 12 July 2016.

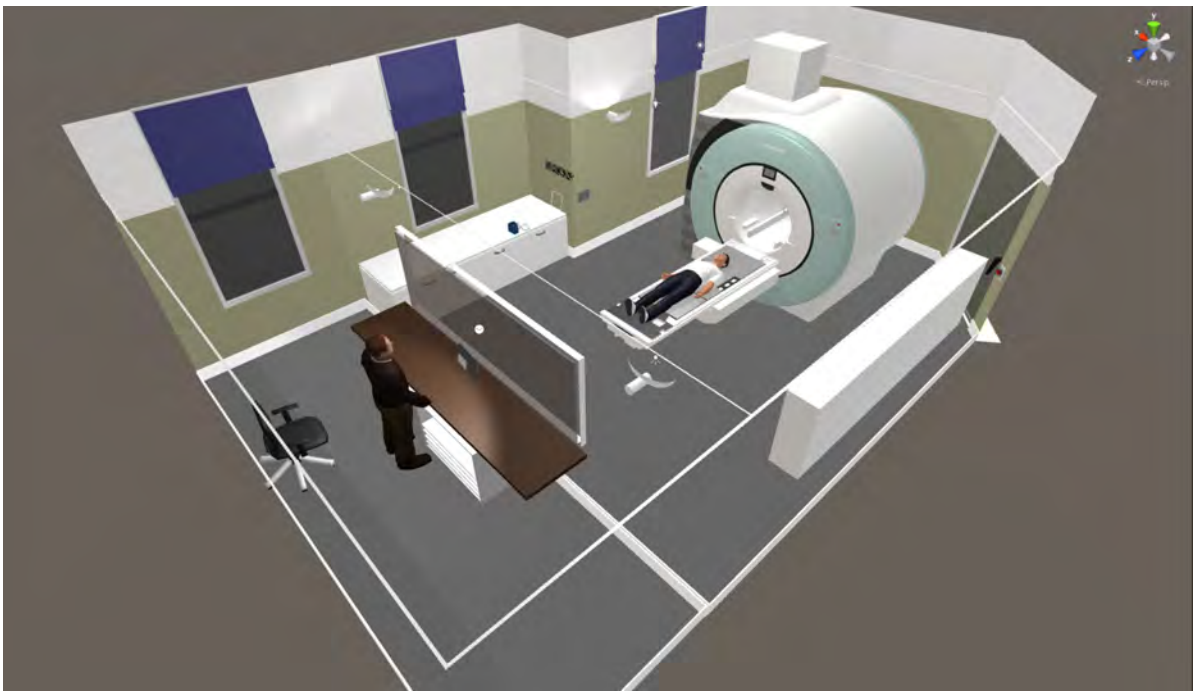


Figure 3.5: Prototype 3D model of MRI and control room

I designed a bespoke system and oversaw development of the VR application written in Unity using a 3D model of the MRI scanner and head coil from manufacturer, Siemens. Photographs taken from a similar facility while it was in the installation phase were used to inform the 3D modeler of the target environment.

The requirements demanded a lightweight portable solution which could be executed in the hospital for in-patients but mobile enough to consider future development to take home as an alternative preparation for the medical procedure. After consideration of alternative head mounted displays, the Samsung Gear VR was selected as it needed only a mobile phone for display and was broadly accessible to consumers. The application was packaged to a Samsung Gear VR for usability testing in the Lab environment with the first 'bucket' prototype (made by medical engineers from the hospital) being replaced with a second cardboard refinement of it after user continuous improvement. I iteratively enhanced this throughout the Hospital pilot study with a third cardboard version leading to the creation of prototype 4, a robust final piece ready for user experiment.

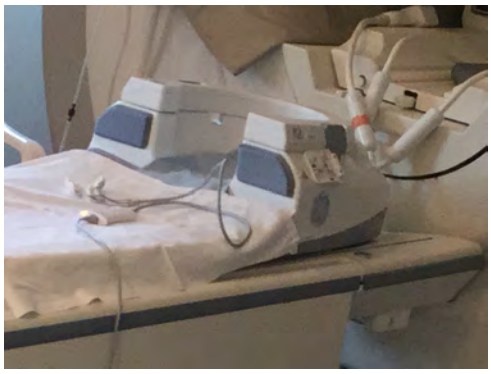
My contribution throughout this study has been to define the what in system terms and integrate the separate parts to create a coherent VR system capable of replicating the patient experience of an MRI brain scan. This has covered all aspects of user experience (UX) development and working with a wide variety of specialists from neurology consultants, MRI technicians, nurses and medical engineers at the Hospital to academic staff and fellow classmates in the Lab to gather the necessary knowledge to create the bespoke experience. Further detail of the development can be found in the subsequent chapters titled VR System and Usability Testing.

3.2.3 Development of Experimental Procedure

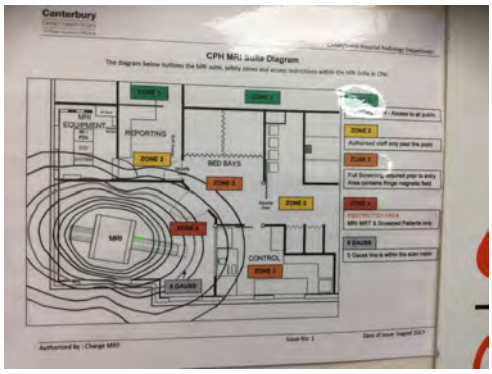
In parallel to the mobile VR application development, the approach to running the experiment in the hospital environment was progressed in the following stages:

- Establish how to test for anxiety using
    1. self report questionnaire
    2. physiological measure (including skin conductance sensors
- Test skin conductance sensors in MRI room
- Draft procedures for use of questionnaire
- Draft procedures for use of sensors
- Record data from sensors and evaluate
- Create physical lab environment
    1. Replace tilt-back chair with long couch
    2. Introduce laying back into a physical head brace
    3. Introduce skin conductance sensors to record anxiety

Attention focused on recording anxiety using self-report, both qualitatively and quantitatively and the quantitative method of physiological sensors. The State Trait Anxiety Inventory short-form was used for the six questions to be asked before, during and after the experiment. Skin conductance was selected as this was simple to use and from a non-sympathetic source (Bishop & Forster, 2012). One of the first actions was to test that the sensors could function in the MRI room.



(a) IOM white sensor with green light shining confirming ready for use



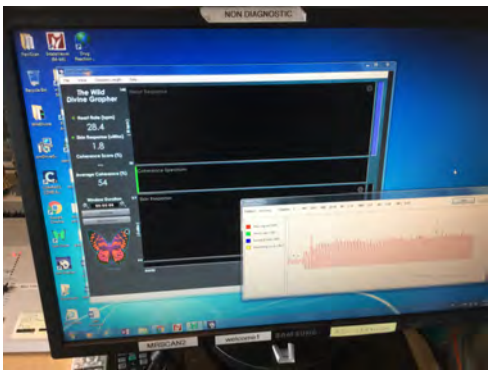
(b) Green dot shows position of IOM within MRI room

Figure 3.6: Testing of skin conductance sensors in MRI room

A volunteer member of staff then wore the sensors on their fingers. Some distortion of the heart beat displayed but numbers looked feasible. This was then double checked with a heart rate monitor which was MRI friendly but display only (unable to record). A decision was made that the sensors should be located as far as possible from the electromagnetic field, so for the pilot, sensor would be attached to the toes.

A pilot trial was run to confirm everything got measured accurately and the process flowed within the day-to-day running of the hospital.

(a) Sensors on left fingers



(b) IOM Grapher showing positive skin conductance and heart rate readings from scanner room

Figure 3.7: Voluntary staff testing of skin conductance sensors in MRI room

3.3 Overview of Usability Study (Pilot)

The aim of this pilot study is to gather emotional state during the virtual reality simulation of a brain scan compared to the MRI experience and incrementally improve until medical specialists involved in the study agree the system is ready to be taken to the experimental stage. Thus completing usability testing to capture usability problems and issues.

Initially tests were run with ten non-patient participants in the HITLabNZ to establish prototypes. Then with twenty MRI and Neurology staff involved in patient care at Christchurch Hospital to test out the prototypes and enable refining of the process as it is vital this research study does not detrimentally affect the day-to-day running of the MRI department.

Finally, tests were repeated with the first three patient participants scheduled for an MRI brain scan. This final stage was a point at which to pause in the actual experiment and reflect on the data gathered so far.

The prototype undertook a pilot trial in three parts:

1. in the lab,
2. in the hospital with staff and
3. in the hospital with patient volunteers.

3.3.1 Stage 1: Lab Pilot Study

A lab pilot study was conducted to establish

- the existence and removal of experimental flaws,
- confirm the process for measurement and
- bring the prototype to a position where it was ready to move to the next stage for specialist user input.

3.3.2 Stage 2: Hospital Pilot Study

The hospital pilot was conducted to establish the system was

- refined for environmental features (vibration, user positioning and restriction of movement)
- fit for purpose
- a realistic simulation of the medical procedure
- compatible with the MRI scan operating procedure
- acceptable to the MRI specialist staff
- acceptable to the doctors and general nursing staff whose patients would be approached.
- known to and fully supported by neurology consultants, doctors, and nurses responsible for patient care of the participants approached.
- known to and fully supported by MRI department, covering all staff responsible for patient care of the participants involved.

3.3.3 Stage 3: Hospital Patient Pilot Study

Stage three of the pilot study was conducted on patient volunteers to establish the refined system was

- fit for purpose with the target participants
- enriched by feedback from those with no prior knowledge of the experiment or environment
- tested with the MRI scan process included.

Note: Due to ethical conditions, coupled with the scarcity and cost of resources, running of the full patient's MRI scan could only be carried out for patient volunteers at the time it was required for their medical care. The types of scan carried out during stage two equated to maintenance checks on the sensor with a member of the MRI or research team.

This has been detailed in the next chapter, Chapter 4, Useability Study.

3.3.4 Researcher's Findings from All Stages of the Pilot Study

The first stage of pilot, in the HITLabNZ involved ten participants. Stages two and three in the hospital had twenty three participants, twenty medical staff of whom seven were MRI specialists and three were patients naive to the process of MRI. Research has shown an optimal level of usability testing can be achieved with eight expert users who are specialists in their field, (Wynd, Schmidt, & Schaefer, 2003) and (Polit & Beck, 2006) support this. For our study, seven experts in MRI and two in radiology were engaged.

3.4 Hospital Protocol

3.4.1 Preparation

The Neurology ward in Christchurch Hospital is the main feed into patient MRI. An initial meeting was held with medical staff of the Neurology Department at Christchurch Hospital to walk through the proposed experiment via a role play demonstration of the simulation with a doctor volunteer. The purpose of this meeting was to give a hands-on user experience, to validate the approach, identify problems and answer questions. This resulted in amendments to the consent forms to ensure screening of vulnerable patients and the process agreed. The researcher then worked closely with nursing staff on the neurology ward to understand the day to day routine, and establish a working procedure to invite MRI scan patients to participate. This was repeated for each of the main donor wards the MRI suite received patients from. Often the charge nurse invited the researcher to their handover meetings to maximise communication and facilitate questions.

Figure 3.8: Volunteer Doctor - Neurology ward

3.4.2 Existing Hospital Protocol

The experiment needed to fit into the existing hospital protocol for MRI brain scans. The researcher was accompanied by medical staff at all times and wore an appropriate identification tag for staff and patient recognition. The patient remained under the primary care and observation of MRI technical medical staff at all times while in the MRI scanner in accordance with current hospital protocol.

See Appendix A for the day-to-day operation of the MRI department. The procedure needed to fit in with this.

3.4.3 Development

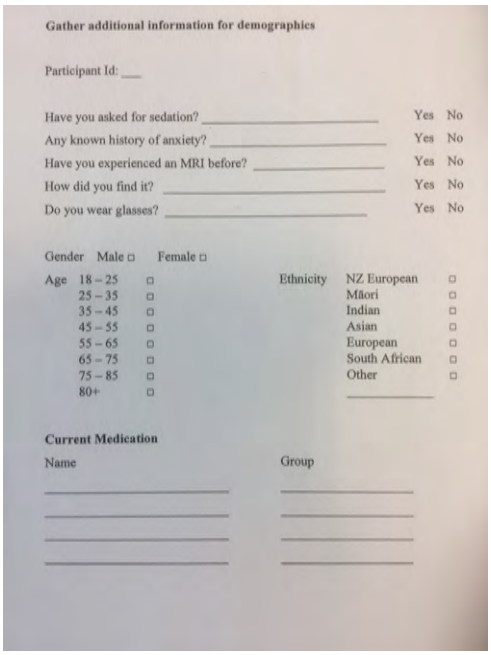
A second observational study took place. The researcher stayed in situ at the hospital for a few days while a number of patients experienced their MRI scan. This included a general anaesthetic sedation (GA), a child after play therapy and adults of various ages. This brought a sharp focus on the time critical use of all resources and the very dynamic flow of patients through the MRI suite. Key resources were not just the scanner but medical and administrative staff from various departments and the patients themselves. All were working to achieve maximum efficiency at minimum cost. Thus setting the margins and constraints within which the experiment was to run and a hospital protocol defining this to be written.

3.4.4 Business Process Change

Introduction of a new MRI scanner both on site and at a neighbouring hospital gave a fixed time period for the user experiment to run. Once the new scanners were in place, out-patients would be directed to facilities in another local hospital and the current load shared between the present 16 year old scanner and a new more advanced version. Eight weeks of pilot run (due to iterative system refinement), led to the allocated time window being halved and an alternative solution to be sought. At significant on cost to the hospital two weekend shifts were arranged to invite 50 additional out-patients from the waiting list. This introduced five research assistants to the team to help support the experimental run. The logistics to support this from all parties were significant. The invitation is shown in figure 3.9.

Figure 3.9: Invitation sent to out-patients for Weekend shifts

3.5 Experimental Data Input



Gather additional information for demographics

Participant Id: ___

Have you asked for sedation? _____ Yes No
Any known history of anxiety? _____ Yes No
Have you experienced an MRI before? _____ Yes No
How did you find it? _____ Yes No
Do you wear glasses? _____ Yes No

Gender Male □ Female □

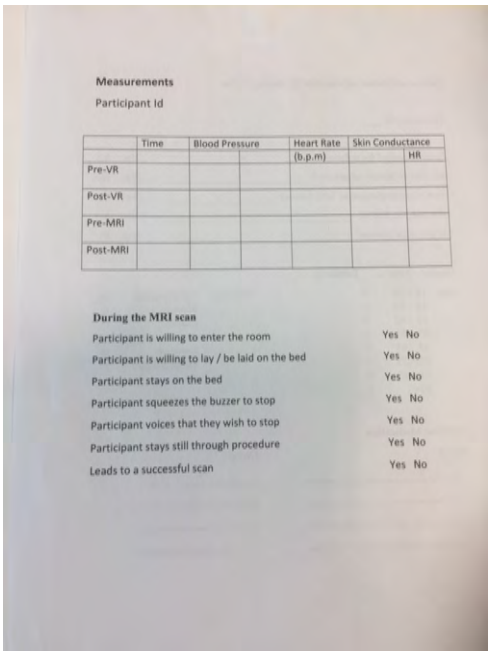
Age 18 – 25 □
25 – 35 □
35 – 45 □
45 – 55 □
55 – 65 □
65 – 75 □
75 – 85 □
80+ □

Ethnicity NZ European □
Māori □
Indian □
Asian □
European □
South African □
Other □
_____

Current Medication

Name Group

(a) Demographic information collected



Measurements

Participant Id

	Time	Blood Pressure		Heart Rate (b.p.m)	Skin Conductance	HR
Pre-VR						
Post-VR						
Pre-MRI						
Post-MRI						

During the MRI scan

Participant is willing to enter the room Yes No
Participant is willing to lay / be laid on the bed Yes No
Participant stays on the bed Yes No
Participant squeezes the buzzer to stop Yes No
Participant voices that they wish to stop Yes No
Participant stays still through procedure Yes No
Leads to a successful scan Yes No

(b) Patient measurements and activity

Figure 3.10: Measurements captured per participant and Binary responses for During MRI scan

Forms for collecting demographic data and measurements are shown in figure 3.10. For demographics, age, gender, ethnicity, history of MRI, history of anxiety, current medications, (name and group) and responses to the questions "Have you had a previous MRI scan", "Have you heard of others' MRI scan"?, "Do you have a history of anxiety"? and "Have you asked for sedation?" were gathered. Coding details of these fields are at Appendix C table **??**.

The second form contained measurements detailed earlier in table 6.2. The recorded patient activities in the MRI room are; Participant is willing to enter the room, wiling to lay/be laid on the bed, stays on the bed, squeezes the buzzer to stop, voices that they wish to stop, stays still through the procedure and leads to a successful scan. All answers are Yes or No options.

Data recorded during the experiment required subsequent coding to put into a format for statistical analysis as shown in table Appendix C3 **??**. Original experimental analysis was carried out on a spreadsheet, then coded and put into CSV format for statistical package readiness.

3.6 Experimental Results

Data was transcribed from the manual sheets into two spreadsheets containing high level data of potential participants (population) and detailed level of those who agreed to take part (participants). The file was manually checked from the pages by a four eyes procedure, sighting both the original and the spreadsheet entry. Input from the spreadsheet was coded and put into CSV format for statistical package readiness.

3.6.1 Data Quality of Results

Patients not meeting the criteria were removed from the study when identified as unsuitable. It has been observed that in some instances data values for valid participants were missing. A simple way to handle missing values is to exclude them, but this can only be done if these values are missing at random (Yang, Li, & Shoptaw, 2008). Lack of data in this study was due to problems encountered during the process and therefore could be classed missing at random (e.g. the grapher software measuring skin conductance was not fully set-up at the time when the patient finished their MRI scan). Where the physiological data was not complete, these rows were removed from the study in order to prevent skew.

3.6.2 Analysing the STAI Y-6 Questionnaire

Answers to the six questions needed to be analysed to create a single mean average value representative of the participants' input. The following shows an example of the calculation where the original values are reversed if they are positive questions 4=>1, 3=>2, 2=>3, 1=>4 to give a re-scored value. The prorated mean is then equal to the sum of the rescored values multiplied by 10/3 (as the six questions were originally 20 in the State Trait Anxiety Inventory i.e. 20/6).

Item	Question	Response Value	+ve or -ve	Rescored Value	Total	Mean	Prorated Mean
1	I feel calm	4	positive	1			
2	I am tense	3	negative	3			
3	I feel upset	1	negative	1			
4	I am relaxed	4	positive	1			
5	I feel content	4	positive	1			
6	I am worried	1	negative	1			
7				0	8	1.33	26.67

Figure 3.11: Calculation to establish a single value for STAI questionnaire response for each stage (before, during and after).

3.7 Summary

This chapter has covered four stages of development; development of the prototype, usability testing in the lab, on-site pilot in the hospital with staff involved in patient care of potential study participants and finally on-site pilot involving the MRI scanner and patient participants.

Once it was at a stage visually to take to the next level, development moved to the hospital environment to clearer define and work through the environmental requirements of physical location, equipment,

Participants with missing data

Id	Group	Missing Values in General Anxiety Score (GAS)	Missing Values in State Trait Anxiety Score (STAI)	Missing Values in Skin Conductance Level (SCL)	Missing Values in Heart Rate (HR)	Blood Pressure (BP)	
2	Experimental			Before and After			
4	Experimental	After	After				
12	Experimental			Before and After			
16	Experimental			After			
40	Experimental	Before, during, after	During, after				
	Experimental						
6	Experimental	All VR					Removed prior
48	Experimental	Before, during, after VR	Before, during, after	Before, during, after	Before, during, after		Removed prior
1	Control			Before, after		After	
3	Control			Before, after		After	
5	Control			Before, after			
7	Control				Cuff popped off	After	
29	Control			Before, after	Before, after	After	29

The greyed out rows are withdrawn participants (Id 6 and 48).

Participant Id 40 was ignored during statistical analysis as they do not have a value in the STAI during field.

Figure 3.12: Input data missing at random

vibration and sound. Hence the prototype continued to develop through usability testing. The lab testing brought the proof of concept to a point where it was ready to go into the hospital for expert user testing and system refinement.

Hospital staff enabled development to replicate the current medical procedure to a standard felt appropriate for the given time and financial constraints. Running this with three patient volunteers uncovered further significant findings; the removal of skin conductance sensors in the scanner room and the introduction of measurement of skin response, blood pressure and heart rate pre and post experience. Many alternatives were investigated for the use of physiological measurements. Time and financial constraints limited selection to those currently available within the lab and hospital MRI environment. Details of options can be found at Appendix C section 5. The IOM sensors were selected for use, plus the use of the MRI department's blood pressure monitor for heart rate (and blood pressure). Also, questionnaires were embellished so that these could be simply administered without intervention. Experimental results showed two cases where data values were missing at random and subsequently could be ignored in the statistical analysis. Usability testing is documented in the following chapter, Chapter four. Chapter five gives further detail of the VR system developed.

Chapter 4

Usability Study

Initially tests were run with ten non-patient participants in the HITLabNZ to establish prototypes. Then with twenty MRI and Neurology staff involved in patient care at Christchurch Hospital to test out the prototypes and enable refining of the process as it is vital this research study does not detrimentally affect the day-to-day running of the MRI department.

Finally, tests were repeated with the first three patient participants scheduled for an MRI brain scan. This final stage was a point at which to pause in the actual experiment and reflect on the data gathered so far.

4.1 Lab Pilot Study

4.1.1 Lab Experiment Setup

The lab pilot was carried out in the Student Lab in HITLabNZ. The setup can be seen in figures 4.1 and C.1.

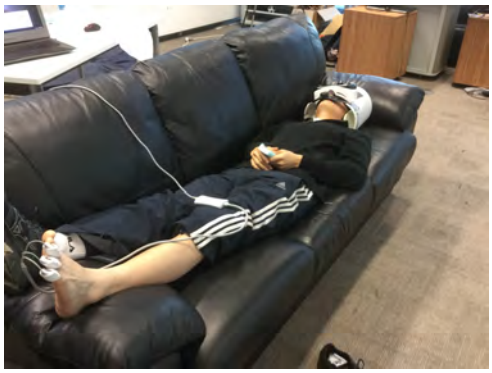


Figure 4.1: Participant in experimental setup - lab iteration 1

Equipment used was a 3 seater couch, prototype 1 (P1) head brace and earmuffs, chair and disposable cleaning products. A small table was placed behind the black couch to hold the laptop, iPad, paper towels, wipes, participant forms, pen, headphones and head mounted display with phone. Prototype 1 neck brace was kept out of sight. A chair was positioned in front of the bed for the Researcher to sit on. The IOM device software and Grapher were opened and checked to be working correctly.

After feedback the head brace was remodeled and the participant repeated the experience. The head brace evolved as participants gave feedback. This can be seen in figure 4.3showing P2 and P3 versions.

Figure 4.2: Sensor graphical display in experimental setup - lab iteration 1

(a) Prototype head brace P2

(b) Prototype head brace P3

Figure 4.3: Lab participants in experimental setup

4.1.2 Lab Participants

Ten participants from the Lab took part in this Study. Participant number 8 is an expert in the field of Virtual Reality. Participant number 9 is a specialist in the field of User Design. Both participants used Prototypes 1 and 2 for the neck brace. All would welcome the opportunity to take part in a repeat study once application and study modifications have been made.

4.1.3 Lab Key Findings

Participant 8 was asked: "How did you feel during that User experience?" and responded – “I felt uneasy. I definitely felt like I was really going into an MRI. I have already done it once before so; it reminded me a lot of when I was in there”. As cool as I can see this is; this is a very intense simulation because it is constraining but that is going to be different for different people and different types of heads...which is not good for a study and manually putting this on someone is going to be variable. This is fact, there is no way to get exactly the same on every patient. I would take a piece of this (white plastic from the bucket front) and mount it here (underneath the headset) so that when I have this on, I always have this thing in front of my face”. That way the visuals combine with me feeling my breathing; and that will work for everybody – and just get rid of the bucket. It does not physically squeeze their head inside the MRI machine, it is just really close to their head.” It makes a lot more sense. There is too much variability here.

As the gatekeeper, how do you feel about the quality of what we have got here? “I think the graphics are not high quality, I think that would require another level of artistic ability. But, I actually think it is very compelling the way it is. I don’t think that you need hyper-realism in order for it to be believable. This is my opinion. The guy in the control room does not look very realistic, but the main thing is that I am sitting there and this motion lining up and the audio is lined up the same way. I see it in the mirror as well as in the first person. The guy talking to me, it all comes together really nicely I think. Like I said, it brought back some of the feeling I had when I was actually in an MRI machine. The revised headrest was great. Having this combining with the flap, I was thinking about it. I could definitely feel my breath coming back on my lips, which is the goal. Even though it is static, (it does not change when I go in and out), it does not actually change in the gantry either. I have this thing on my head and it stays there. You’re well within the boundaries of a solid prototype. I would not go with the Oculus. You’ll have too much complexity. Neck brace (Prototype 2) – I think this is good - it’s old school enough that it really feels like it is a little intimidating because it is rigid. I think it really gets to the essence of what an MRI experience is like. It is very close. You need to have a well scripted interaction. It seems a little unrehearsed.”

4.1.4 Lab Pilot Discussion

From the nine participant responses on the STAI Y-6 questionnaire, one respondent was not given the questionnaire and one participant did not answer any of the questions. From the seven remaining, one participant showed no change of emotional state except reporting to feel more calm during and after the VR simulation (from moderately calm at rest to ‘very much’ during and after the experience). This is the converse to the hypothesis. Of the remaining six participants one felt much more calm and relaxed after, although for this individual, results were not available during the experience, (this was not completed by the participant). This could have been as the result of miscommunication between the researcher and the individual or oversight by the researcher. Also, researcher oversight resulted in one further participant not completing the ‘before’ and another not completing the ‘at rest’ questions leaving just three participants who completed all four stages of the questionnaire. That said, looking at the individuals does lead to useful data being gleaned.

Three participants have had an MRI before. Two thought the VR gave a good simulation of their MRI experience. One (who could be disregarded as they were outside the Lab conditions, only mentioned it needed to be much louder.)

There was a general trend of the positive emotional states being less positive and the negative ones getting more negative during the MRI simulation. Four participants reported feeling less calm, relaxed or content and more tense during the VR experience. Two participants reported feelings returning to their pre-VR state after the experience. One participant reported being in the same state during and after their experience. The remaining participant reported feeling more negatively affected by the VR scan and after returned to a state midway between their pre and during points. They were significantly more tense and upset (from ‘not at all’ to ‘moderately’) and less content (from ‘very much’ to ‘not at all’) and remained ‘somewhat’ afterwards on all three measures.

It is recommended that the full version of this questionnaire (Spielberger, 1983) is analysed by a level ‘C’ clinician. The short form used in this study (Marteau & Bekker, 1992) may also fall under the same category. Following advice sought internally within the University, it was established that a mean value be calculated using scores from the six questions posed.

In order to answer the research question stated in the Ethics application “Can an immersive virtual

reality (VR) simulation be used to predict whether an adult patient will endure a MRI brain scan procedure with no movement?", the measure of 'after' is not required, neither the follow-up of the same question one month on (as mentioned in the Ethics submission).

Concerning reproducibility, the pilot revealed some confusion between 'at rest' and 'before'. Participants reported that they seemed to be being asked the same thing without a defined difference between stages. Considering the first measure 'at rest', in the experiential setting, this introduces variability between in-patients (who would be measured on the ward) and out-patients (who could be measured in the waiting room). Considering what needs to be established here, is it necessary to collect the anxiety range with thresholds for each individual or is it only necessary to know what level is associated with being able to remain in the scanner without moving? A better measure may be to take the anxiety only 'before' as this can be verified as when the participant is ready to start the simulation/procedure. The important thing is consistency between all participants and sufficient data to evaluate the results. A before measure, when compared with the after, enables an understanding to be gained as to the change in emotional state, the delta, induced by undertaking the MRI scan procedure (be it virtual or real).

4.1.5 Researcher's Findings from the Lab Pilot

For the VR experience, presence also needs to be measured. Does this also make sense for MRI? (e.g. In the example where the participant has closed eyes and is just trying to block out the world to get through the procedure (as one VR participant mentioned to me they had done in a previous MRI experience). Conducting the VR simulation was disjointed because the researcher was unable to see what the user was seeing. This resulted in interruption of the simulation to turn the user up to 180 degrees to correctly align them with the scanner before entry. This had a negative impact on the user's experience. A better solution would be for the researcher to see on their laptop a window showing what the user can see in the head mounted display. To achieve this on the Samsung Gear VR involves a number of manual steps which increase risk of human error. Theses steps are detailed at Appendix C3 (Method Detail).

Latency between 5 to 20 seconds is experienced which means the researcher needs to wait for this period of time before seeing what the user can see now. This impacts negatively on the smoothness of the experiment. The least obtrusive option may be to use the Oculus Rift. By default this displays the application on a PC screen as the user watches in the Oculus headset. Ear phones are included in the headset so these could be replaced with earmuffs. Other equipment may be plugged straight into the PC to leave the user less cluttered. This will be taken into Hospital trial for consideration. Here a PC is necessary and it needs to be one capable of running Oculus (with a high spec graphics card). High end laptops capable of this currently increase the cost of investment by 3000 NZD. Also the camera needs to be disabled as this competes for the user's position over the head tracking (which is all that is required by the VR program. That said, the user experience is of a higher resolution and less strain on the eyes.

4.1.6 Lab Pilot Conclusion

From these results it is established that the VR simulation is an adequate prototype to continue with the Pilot Study in the Hospital. The start of this stage will be dependent on resolution of the issues for correction given earlier in this document.

4.2 Hospital Pilot Study 1 - Staff Participants

Throughout this section HP1 will be used to abbreviate the second stage of the pilot study held in situ with staff volunteers.

4.2.1 Staff Pilot Experiment Setup

The hospital pilot was carried out in the Radiology Department outside the MRI suite at Christchurch Hospital, Christchurch, NZ.

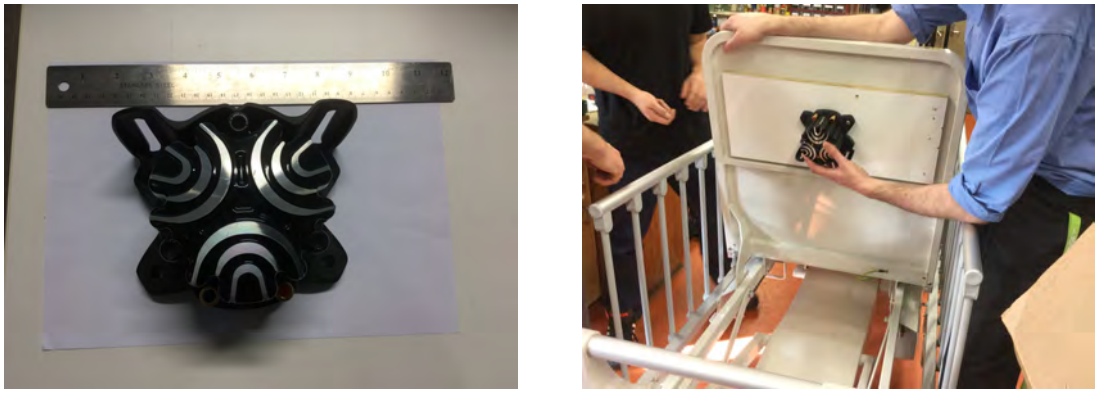


Figure 4.4: Buttkicker screwed to the underside of the bed

A buttkicker was brought into the hospital as in 4.4. To mount it, a wooden board was attached underneath the top panel of a trolley bed using eight screws (head end on the bed surface). Self-tapping screws were then used to attach the butt-kicker securely to the middle of the panel underneath for movement in an up/down motion. A thin smith mattress replaced the thicker one normally used as seen in figure 5.4.

The purpose of the butt-kicker was to simulate the vibrations received from the MRI scanner both as they bed enters the scanner bore and also during the scanning process. The intention was that it will be turned down to the gentlest setting and respond to the lower frequencies given by the audio file to simulate vibrations. The bed was taken up to the test area in the Radiology department and the amplifier and pre-amplifier set up. A trolley provided storage for the audio equipment beside the bed. The bed was put in part of a general area which included a waiting facility and across from where other patients are in transit between CT and other scanning rooms.

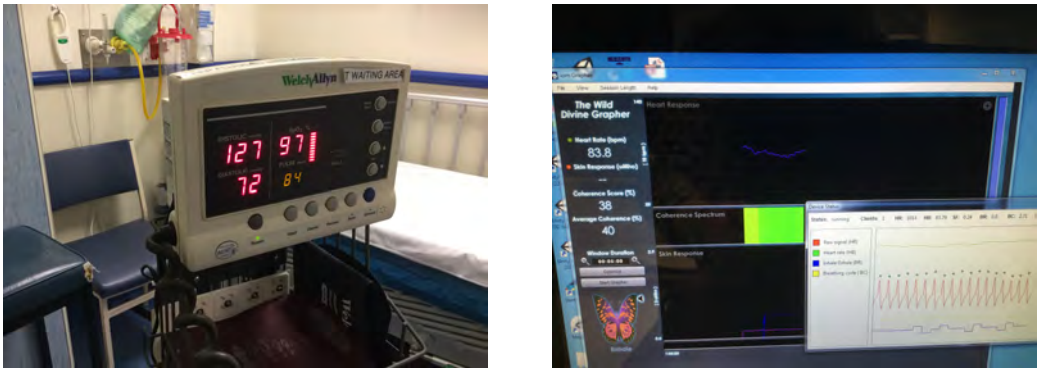
The participant setup can be seen in figure 4.5.

Figure 4.5: Staff participant in experimental setup - hospital iteration 1

It was noticed that a folding wall could be pulled forward to encapsulate the area more to form a room with a curtain at the front and walls on the other three sides. This proved to be more suitable and blocked out some background sound. The room only had space to accommodate the trolley and bed alongside but was found to be a suitable solution once the participant was in place. If a patient needed to be transferred from their own trolley bed this would need to take place prior to pulling the wall forward.

4.2.2 Calibration

There are three sensors on the device, two for skin conductance and one for heart rate. The heart rate sensor was checked against a monitor used on the ward in the hospital to show current heart rate and blood pressure. This additional sensor was put on the toe to enable comparison. No medical device to



(a) Blood Pressure monitor showing pulse reading of 84 (b.p.m.)

(b) Grapher displaying heart rate of 83.8 (b.p.m.)

Figure 4.6: Calibration of heart rate

measure skin conductance was available at the hospital so sensors were sourced from outside. Another skin response sensor of the same type (blue) from the same supplier (Wild Divine) was ran at the same time to compare the quality of the data gathered, yielding a difference of approx 1 Siemen higher on the original blue sensor. (For skin conductance sensors, precision can be improved by measuring a voltage and relating that to what the operating temperature of the sensor must be (Villarejo, Zapirain, & Zorrilla, 2012)). The original (blue) set of sensors was used throughout the experiment (the second set, which was not called into action, provided a backup in case of failure).

On the VR headset, a dial on the top was self-adjusted by the participant to adjust the focus for the individual user. Participants chose whether or not to wear their glasses. Both conditions were valid for use in viewing through the HMD and choice was down to comfort of the wearer.

4.2.3 Hospital Staff Participants

The four participants mentioned here yielded significant findings. The first participant, a fellow researcher and part of the MRI team, experienced the VR simulation with the Samsung Gear VR. Oral Feedback given included 'too comfortable, need further restriction on head'- akin to prototype 1 head brace. Fitted actual MRI head coil on principle researcher to show how tightly this held the patients' head. Also, the application looked too relaxing with the cherry blossom on the ceiling. Negative feedback was given on the use of the word 'Welcome' and advice that the colour of the scanner in the 3-D model provided by

Siemens should remain the original green (not cream). They also received the VR experience using an Oculus DKII headset (a prototype to the consumer version) to gather their opinion. For this participant, the headset was very uncomfortable at the base of their forehead and the participant strongly advised not to continue using due to discomfort. It was clarified that some participants may have had brain surgery the day before and need to be treated with the utmost care so a delicate balance was required.

The second and third participants were experts in the operational MRI process and handling of the MRI patients. With no prior knowledge of the study, the second participant experienced the VR simulation twice, first with prototype 1 head brace and then with prototype 2 giving feedback on suitable design. The third participant assisted with refining the vibrations of the VR system to simulate the feeling of a patient when in the MRI scanner. The initial recording had been on an iPhone and not of sufficient quality to enable sound engineering. Using specialised equipment, a new recording was made of three standard configuration sequences and then different waves were trialled. The participant laid on their back in the experimental position, with head brace in place and reported on which combination best replicated the vibrations in the MRI scanner, finalising on the combination of a 15 Hz square wave and a 20 Hz triangle wave.

The fourth participant was an expert in radiology and very keen to experience a head MRI scan as a member of their family had already done so. After the VR experience they reported being very pleased that they had tried it but definitely did not want to have a real scan now as a result. The graph in figure 4.7 shows clearly their skin conductance response, one very similar to that quoted in van Minde's work regarding anxiety in MRI (van Minde et al., 2014). It could be concluded from this that in this instance the participant's response was correlated to that they may experience in the real MRI.

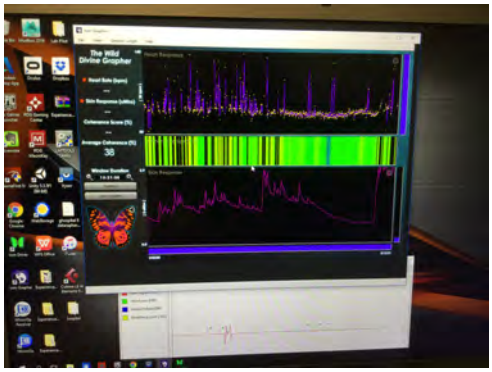


Figure 4.7: Grapher reading from pilot participant

4.2.4 Researcher's Findings from the Hospital Staff Pilot

Researcher's findings included the equipment was cumbersome to bring into the MRI suite.

Ideally all testing of the software and audio equipment would have been completed in the Lab and resolved before bringing onto a customer research site. This has proven impractical with no access to the medical trolley bed in the lab.

An additional surface (e.g. a wheeled table that could fit over the bed) was required to place research consumables on (i.e. wipes, paper towel and papers).

To enable smooth running and ease of replication the researcher feels it was very important to be able to see what the user was experiencing in case intervention was needed to properly align the user before going back into the bore of the scanner. The screen sharing software did not allow connection from the

phone to the PC. Although both the PC and phone were able to see and connect to the same local Wi-Fi hotspot the PC SideSync software was unable to offer a QR code successfully for the phone to connect to. Therefore screen sharing was not available for this first session of tests. As a solution not requiring screen share, it was proposed that for the next five participants, tests were to be carried out using the Oculus headset. The question would be asked regarding comfort. The participant's eyesight would no longer need to be taken into account as this headset comes with short and long sighted lenses. An extra step would be required to ask the participant whether they need glasses and what for. The headset would then be set up accordingly for them and any necessary calibration would already have taken place. In comparison the Samsung Gear VR has a focus wheel located at the top of the HMD which allows adjustment. This will result in less equipment (that not required is marked with an * on the list at Appendix D. However, a more powerful CPU and graphics card are required so the outcome may result in the use of a suitably specified laptop or a desktop PC from the Lab with a graphics card of at least GE970.

Also, data gathered from the physiological sensors is of vital importance to this research. Objective data, particularly that of skin conductance, is the most necessary to refute the null hypothesis.

In setting up it was found that the USB extension cable did not allow the sensors to work. It is known that they do not work with a USB hub. A previous cable sourced from the Lab had worked successfully so a replacement was purchased.

The harvesting of state anxiety data 'after' was not particularly helpful and therefore, while still being gathered for potential future use, was not considered for statistical analysis in this experiment.

4.3 Hospital Pilot Study 2 - Patient Participants

The third stage of the pilot study involves three patients at Christchurch Hospital who have volunteered to take part. So far, the pilot study has been run with 20 staff participants in the Hospital. This stage follows with the first patient participants undertaking a run of the full experiment, so the VR simulation followed by the real MRI scan with experimental conditions.

Finally, it provided a point to pause and reflect on the process and data gathered to date.

4.3.1 Patient Pilot Experiment Setup

The stage added the second condition of real MRI scan medical procedure, taking place in the MRI scanner room. A camera was set up in the MRI control room focused on the PC screen displaying the grapher and IOM maintenance window. The audio was set to record to pick up events in the scanner room but ensure privacy by not recording the patient themselves. The VR simulation remained unchanged.

For patient participants, the bed was remade each time with fresh linen. A white sheet was laid on the mattress and the neck cushion put into a blue pillowcase (hospital procedure: for patient's head). Use of disposable covers had proven impractical in the staff pilot, so each piece of equipment which touched the patient's skin was cleaned with a separate medical grade disposable wipe. Further detail can be found at Appendix D3.

4.3.2 Hospital Pilot Patient Participants

Participant 21

VR was undertaken with no significant events. Blue sensors recorded consistently low levels of 0.21, 0.2, 0.14. Patient didn't feel any anxiety when in the scanner, but when they sat up they thought they

were going to fall over because of their dizziness. They felt nauseous on arriving in the MRI area due to medication administered up on the ward. They needed to lay down on the bed for a while to let this subside before taking part in the VR simulation. MRI taken with blue sensors. At no point did the skin response display on the grapher window. All observations were from the IOM device window and the grapher SR line displayed. At the start readings were toggling 0.18, 0.19 then to 0.09, 0.05, toggle 0.03 and 0.04, then to 0.11, 0.12, 0.03, 0.04 Data from sensors found to get corrupted while scanning process was happening recording 0.00 on each point. Low scan 0.03 to 0.13 up and down in time with the scan sequence. When scanning stopped, sensors displayed 0.04 The sensors were replaced by the white ones. Data file saved on MRI control machine Desktop: file: Patient 1 bluegrapher.dat. White sensors displayed constant 0.24.during low scan sequences, then to 0.23 when a different sequence. Heart rate reacted to the scan sequence, in sequence to it.

Participant 22

Skin response was taken at rest and recorded a value of 2.0 siemens. The participant went into the MRI scanner first and gave a consistent reading through the process using the white sensors. This was in the vicinity of 1.8 siemens. Once mobile again, their hand was shaking and they reported feeling highly anxious. The white sensors read a value in excess of 9.0 siemens. After a period to restabilize, the participant undertook the VR simulation. Using, the white sensors, readings were 1.2, 1.1, 1.2, 1.3, 1.4 reaching a high of 2.1. It was suspected that the volume was not high enough. Checking the 'at rest' value to be 1.67, the VR simulation was ran again and received feedback that that was more akin to the noise level in the scanner. The Grapher showed variation 1.8 - 2 but no movement on the graph itself which looked like a flat line - suspect the grapher had not been started again. On completion, the sensors remained in place. The reading from them increased as the initial MRI experience was discussed. As the participant started talking, their response went up to 3.9. "Invoked similar feelings but not to the extent of the MRI". Grapher showed a lot more responsive afterwards but that was talking about the previous experience.

Participant 23

This participant was allocated to the control group. They kept the information sheet and provided an address to receive details of the study results. The before questionnaire was completed in the MRI waiting room and the white sensors fitted to toes behind the lead door in the MRI lobby area before going into the scanner. The pre-scan self-report anxiety level (on the scale of 1-10) was 5. Data was recorded throughout the scan and the sensors initially showed variability of SCR tracking around 1.9. The sensors fell off the toes a few minutes into the scan and were put back on by the MRI tech. The sensors remained in place for the rest of the scanning process. On coming out, the self-reported anxiety level at highest point during the scan was 7. Comment "Toes were twitching away - it got to one stage, quite a bit actually - all of a sudden it stopped twitching, I thought they had been taken off". The researcher asked for clarity of the term twitching, the participant replied 'jerking'.

4.3.3 Patient Pilot Findings

It is established that the blue sensors used for the last ten pilot participants are not suitable for use in the MRI scanner itself. Therefore another way needs to be found.

Focus returned to the sensors used prior to the modified blue ones. These are the white sensors also from Wild Divine with clip-on housings for fingers and toes. Earlier tests had shown the reading did not show obvious signs of interference during the scanning process. Looking across all three participants in the scanner, readings were flat lining during the scanning process.The heart rate sensor reacted differently with it's graphic line replicating that of the scanner sequence as viewed on the raw data IOM device window. On completing the full MRI session (of an hour) monitored with the white sensors, one participant mentioned their toes had been twitching. This participant reported the level got to the point where they could hardly put up with it any more and then he reported it stopped. The stimulation effects were suspected to be peripheral nerve stimulation (PNS) which while not hazardous but can cause substantial discomfort in excess of the sensation threshold by 50 to 100 percent (McRobbie, Moore, Graves, & Prince, 2017) For this reason, and the potential for the SCR data to be compromised I removed skin response monitoring in the MRI scanner room and therefore also in the VR simulation. It was felt wise to retain the camera recording from the control room to ensure a log is kept of the events in monitoring. This was particularly important in a medical environment where circumstances can change swiftly and unpredictably.

4.4 Conclusion of Patient Pilot Findings

In addition to confirming the process flow, these three participants have uncovered significant findings for the running of the experiment.

- Firstly, the removal of both the blue and the white sensors in the MRI scanner (and therefore also in the VR simulation).
- Secondly the introduction of the repeated measurement of skin response, blood pressure and heart rate pre and post experience to replace the former.
- Thirdly the embellishment of the patient questionnaires so that these can be simply administered without intervention.

Thus the usability study enabled the full development of the VR system and supporting hospital protocol in preparation for the user experiment to take place.

Chapter 5

VR System

This chapter details the main components of the VR system; visual application, audio, vibration and prototype neck brace. It also discusses development of the measurement of anxiety using physiological sensors. Continuous improvement principles were executed throughout which seek 'incremental' improvement over time or 'breakthrough' improvement all at once (Bessant, Caffyn, & Gallagher, 2001).

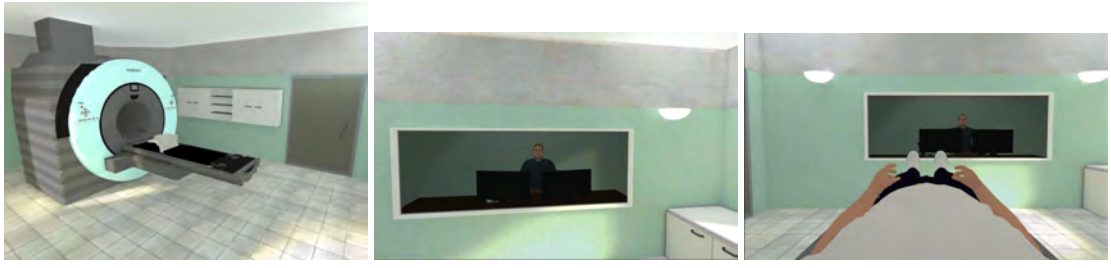
To simulate the MRI brain scan procedure, the VR system needed to be multi-faceted. Each phase of the pilot made a significant step forward in development of the VR system for user experiment. Development steps involved taking an initial prototype and integrating a new virtual model into the Unity application. Refining each step in Unity to create a smoother look and feel particularly the transition between scenes. Redefining how the user interacted from initially touching the button on the side of the Samsung Gear VR to following researcher instructions as guided. All resulted in repetitive packaging of the output APK onto the Android phone until the experience was ready to take to user patients. The main deliverables resulting from each iteration are summarised in this chapter.

5.1 Development of VR application

The application comprised of three elements; the visual application, audio and vibration. The audio also had three parts; replication of sounds in the scanner, medical guidance through the procedure and the sound waves replicating vibration of the trolley bed in the scanner during scanning sequences.

5.1.1 Visual application

The environment was modelled in Unity 3D using Maya.



(a) Welcome to the MRI room (b) Explore to see MRI tech (c) Ready to go in

Figure 5.1: Patient experience

(a) VR model of layout with mirror (b) Position on the bed (c) Moving back into the bore

Figure 5.2: Development of the mirror

A key feature of the Siemens real head coil is an angled mirror which enables the user to view the MRI control room while in the bore. It enables the patient to see what is happening in front of them, including the staff in attendance. This was a key feature to replicate in the application and is shown in figure 5.2 as a black rectangle. When the application is running this showed activity in the MRI room and through the control room window.

The VR application used Unity 3D models of the MRI scanner and head coil from the manufacturer Siemens. Images of the head coil can be found in figure 5.3.

(a) Siemens coil front view (b) Siemens coil left side view (c) Siemens head coil used in MRI

Figure 5.3: 3D Unity Model and real head coil from manufacturer Siemens

Visually, feedback from the first participant of the hospital staff pilot was that amendment was required to remove text and ceiling image and increase audio volume of bed movement. Audibly, the use of headphones meant that the sound of the MRI scanner did not originate from a similar source to the MRI. In reality, sound comes from the moving core and is muted by ear muffs. The ear muffs were replaced in the Lab pilot with headphones to ensure the sound reached up to 120 decibels. However this audio replication is not realistic. The suggestion was that speakers are used next to the bed to play the audio file from the VR application. Ear muffs can then be worn to dull the noise. However this posed two problems, the first, how to ensure that the patient can hear the voice in the application guiding them through the process. Secondly, as the experiment is taking place in a shared area, which is afforded privacy by a curtain, how to avoid disruption to other patients in the waiting area opposite or being attended to nearby (just across the room). In search of a solution, alternative single room areas were investigated, however these posed the risk of the researcher and patient being isolated from medical staff should a medical urgency arise and therefore were rejected on health and safety grounds for both parties. Further audio refinement is detailed in the next section.

To provide visibility of what the user can see, a number of screen share options were investigated, with two showing promise. After working intermittently however, the Samsung screen mirroring feature for Gear VR was found unsuccessful. Vysor (for Android) was more consistent in trials but the complex set-up required (see Appendic C.3 Development Detail, Method Detail) proved impractical resulting in

its withdrawal in the early stages of pilot. The experimenter finalised on the use of sound cues and user responses to guide the experimental process with a bluetooth keyboard providing interaction with the application (via key press of the spacebar). The detail of this can be seen in the 'Researcher script for VR' at Appendix D.

5.1.2 Audio

Audio can be considered in three parts; the sounds of the scanner, the MRI tech talking the patient through the procedure and thirdly, and most important, two-way communication with the patient user. The scanner has a constant background chirp which is the first thing the user is aware of when the headphones are put on. Audio of the MRI tech taking the user through the procedure was the first recording made and applied to the visual application. After this, recordings were made of the MRI scanner machine to give the background noises and of the bed going in and coming out. Then the scanning sequences themselves were originally recorded on a mobile phone which required replacing with professional sound equipment when working with the buttkicker to replicate the scan sequence vibrations more closely. The rest of the section deals with the iterations made to the proposed communication system that was to be deployed to enable communication with the participant.

Firstly the audio equipment levels were tested in the Lab.

Figure 5.4: Audio equipment in the Lab

During the development phase, an attempt was unsuccessful to access the phone's microphone via code in Unity. Another factor leading to the discounting of this method was the accidental activation of the microphone due to extraneous sound sources not in control of the experimenter.

A second method using a traditional microphone, had the advantage of experimenter being in full control of the microphone via an on/off switch present on it. The microphone signal was routed through the amplifier to the headphones worn by the participant. Preliminary trials of the system provided encouraging results. Upon integrating this with the experimental setup though, the microphone levels were found to be too low. The environmental and system specific sounds used as part of the experiment were masking the incoming microphone signal. To overcome this, the gain on the microphone was increased to a level where the experimenter's voice could be heard over environmental cues being provided to the participant via the headphone. This increase in level, unfortunately, resulted in feedback. To ensure complete immersion, the volume of the environmental sounds in the experiment was set at a level at which interference from extraneous sounds was deemed minimal. This resulted in some leakage from the headphones, which was being captured by the microphone leading to feedback. The microphone was withdrawn for the

experiment and natural voice was used to communicate with the user. Volume was operated manually by the experimenter using the bluetooth keyboard and detailed in script at Appendix D.

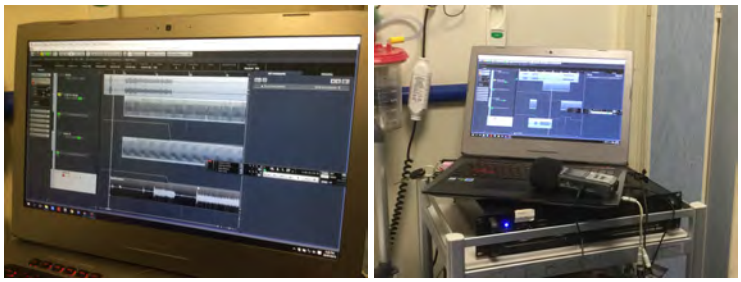
(a) Amplifier (b) Pre-Amplifier

Figure 5.5: Sound equipment

The equipment used and settings are shown in figure 5.5.

5.1.3 Vibration

Steinberg Cubase LE was used to overlay the sound files to reflect test plan scanning sequences used in the MRI machine to simulate the type of vibration most patients would receive during their personal MRI procedure. This is illustrated in figure 5.6. The signal used for the buttkicker finalised on the combination of a 15 Hz square wave and a 20 Hz triangle wave.



(a) Using Cubase (b) Sound files and microphone

Figure 5.6: Sound Engineering

The first three hospital pilot participants who tried it gave feedback regarding the vibrations which were a little too strong. It was agreed the higher frequencies needed to be filtered out. The noise of the bed going into the bore also needed to be turned up to fine tune the vibration in this instance.

5.2 Development of Equipment

5.2.1 Prototype Helmets developed

The final design of helmet was modeled by the medical engineers from the cardboard prototype P3) as is illustrated in figure 5.8. It was an MDF finished rectangular box with a perspex visor. A hole was cut out to fit over the HMD. The breath flap was withdrawn at the first stage of pilot.

Positive feedback was received of prototype 2 in preference recognising that it needed further modification to hold the patients' head in a completely restricted position so they would be unable to move. An

(a) Trying on the real head coil (P1)

(b) Second cardboard box prototype (P2)

(c) Third cardboard box prototype (P3)

Figure 5.7: Prototype helmets

Figure 5.8: P3 and final version P4

alternative of a medical bean bag with vacuum suction was tried out on all three participants and agreed this could be part of further modifications. Also development of something to simulate the enclosed feel was needed. A cardboard model of the helmet proved much more successful. The neck cushion was augmented with sponge to hold the head firmly in place. The front hinge was manually tucked down between the sponge, replicating the tightness felt around the jaw when the head coil was fitted. This is illustrated in 5.7b and 5.7c. Successful use of this resulted in the medical engineers developing a more robust version to the researchers specification 5.8.

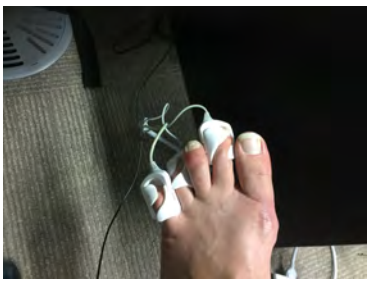
5.2.2 Sensors

Many alternatives were investigated for the use of physiological measurements. Financial and time constraints limited selection to those currently available within the lab and hospital MRI environment. Details of options can be found at Appendix C section 5. The IOM sensors were selected for use plus use of the MRI department's blood pressure monitor.

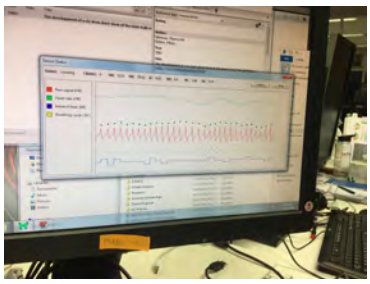
There were four cycles of sensor development. The first, using the white IOM sensors on the fingers and then onto toes after testing in the MRI machine. The Lab pilot used these. Statistics were gathered of mean skin conductance value over the time of the VR scan. Investigations of replacing the cable with fibre optic were unsuccessful due to the bespoke and obselete plug the IOM sensors used.

The second set of sensors were made by a fellow student using an arduino board. This was proof of concept since any device would have to be remodelled by the medical engineers to be MRI compatible. These were compared directly against the IOM. When placed in the same position on the hand the readings were comparable in values. Both were compared on the toe with heart rate sensors attached to the first

(a) Bespoke plug and socket



(b) IOM device window



(c) Heart sensor on middle toe

Figure 5.9: White IOM (S1) the first sensors used (Lab pilot)

(a) Arduino sensor

(b) Normal use on hand

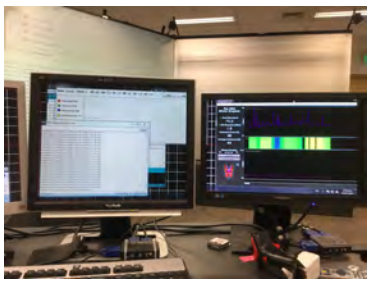
(c) IOM and Arduino

Figure 5.10: Arduino (S2) lab evaluation of second sensors

two fingers of the left hand. The data displayed on screen was comparable with the arduino reading heart rate of 75.3 and skin conductance of 1.8 and the arduino reading heart rate of 76.92 and skin conductance of 1.83. In the mRI the requirement is for the sensor to be as far away as possible from the scanner bore.

(a) Arduino and IOM sensors on left foot

(b) With unseen heart sensors on hand

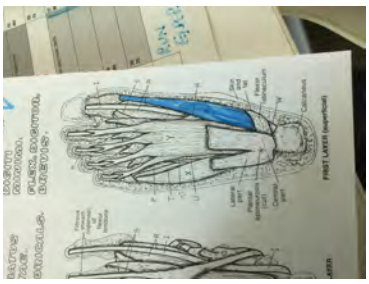


(c) Grapher and Arduino show similar data

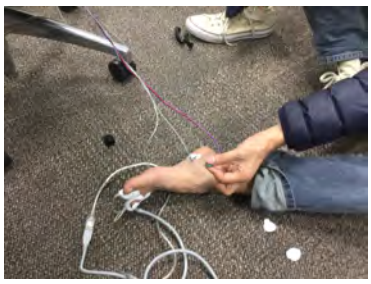
Figure 5.11: Comparison of sensors

Placing arduino sensors on the foot palmer site gave a much higher recording which led to consideration of this in preference to the toes because fitting onto the toes proved cumbersome and a little intrusive during pilot. This was in line with findings from Fowles et al recommending placement over the abductor hallucis recording from 16 to 40.

A set of blue sensors were sourced from the Hospital and these compared against the white IOM ones to confirm they could be used if needed as a backup. The blue device showed a slightly lower heart rate and skin conductance so maybe they were less sensitive. The Grapher software showed values from the white IOM of heart rate 82.8b.p.m. and skin conductance of 2.3 microS compared to the right screen blue IOM values of heart rate 76.4 b.p.m. and 3.4 microS. Both graphs showed very similar trends though maybe a marginal difference in sensitivity. This is illustrated in figure 5.13.



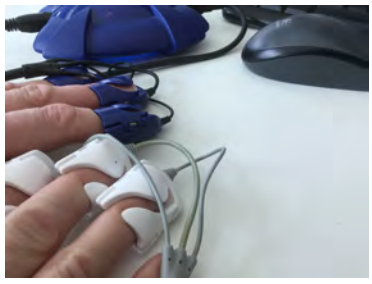
(a) Palmer site on foot



(b) Arduino on palmer site

Figure 5.12: S1 and S2 on foot

(a) Testing blue and white IOM



(b) Close up

(c) Data comparison (blue left)

Figure 5.13: Comparison of sensors with blue IOM from hospital

Replacement white IOM sensors were ordered for the experiment. It was then found that the existing ones had become obselete and the new model was not suitable for the experiment as the heart sensor had been replaced with an ear clip so could not be worn away from the bore. So sourcing was from a third party. However on arrival the set were identical to the ones previously tested from the Hospital. Having experienced difficulties with the use of the finger clips on toes in the hospital pilot the medical engineers assisted in replacing the finger clip with a flat disc so that the sensor could be applied to the inner arch. Various options were tried out to hold the sensors in place including a part insole orthotic. A foot cradle was finally 3D printed to hold a piece of neoprene covered memory foam. The disks were placed on the pad and applied to the inner left arch. This was secured to the underside of the foot with a velco strap and performed well in trial.

(a) Foot cradle and pad

(b) Flat blue IOM sensors

(c) Sensors in situ

Figure 5.14: Restyled skin conductance sensors (S3)

Both sensors were offered to staff participants during pilot to get feedback on preferences. For some S3 was preferable usually due shape of the foot. The velcro strap was found to irritate some although this could be relieved by lining the strap with a piece of neoprene. For others their toes made good contact with the S1 sensors.

(a) S3 in staff pilot

(b) S1 after S3 caused soreness

Figure 5.15: S3 and S1 comparison

However S3 proved problematic in the scanner and the original white IOM ones were returned to use for the Patient Pilot.

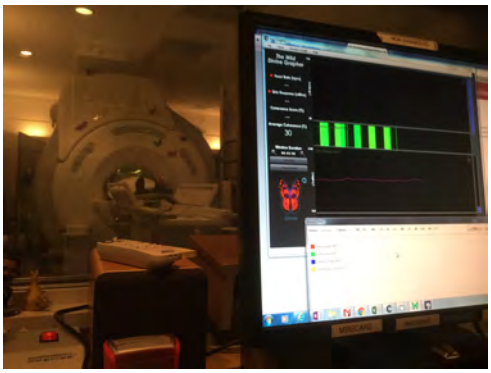


Figure 5.16: Patient Pilot trial using white IOM sensors

Use of the skin conductance sensors in the hospital staff pilot yielded mixed results. For the first participant, the IOM device was not being detected. It was later found that this may have been due to more than one IOM driver running (it is a known issue that multiple drivers need to be closed). The second participant was unsuccessful with a constant reading of 0.2. The third participant showed promise with positive readings with skin conductance being displayed on the grapher for all of the participation time. generally, one the sensors were fitted well in place, readings could be taken. Data files were collected for all subsequent participants. Even if the grapher did not show readings data was successfully written to the data files for analysis.

The white IOM device maintenance window was used to record the SF and HR figure for skin conductance and heart rate respectively if the grapher did not display. A camera shot was taken of the reading and values recorded on a separate data file for analysis.

5.2.3 Findings from Hospital Pilot

As the pilot ran, the VR system was iteratively improved with participant feedback until the point at which it was considered by the MRI team lead to be a good enough reflection of the real MRI procedure. Improvements have been incorporated into the earlier sections specific to the item. The equipment selected to be used for the study is shown in tables 5.1 and 5.2.

Table 5.1: Equipment selected for study

Equipment	**Hardware**			
	VR Application	**Audio**	**Vibration**	**Sensor**
Medical Trolley with sheet	HMD Samsung Gear VR	Zoom H4n portable recorder	Buttkicker Concert (240v)	2 GSR Wild Divine Blue IOM flat sensors
Prototype 4 head brace with pillow	Samsung Galaxy S6 edge+ mobile phone	Non-noise cancelling headphones	Pre-Amplifier	Heart rate sensor - incl. in above
Blood pressure monitor	power cord		Amplifier	USB RF shielded 5 m or longer extension cable
chair	5 socket power extension		2 Audio leads (red/white plugs)	Reconciliation sensor - Hospital's own MRI friendly heart rate display sensor
Anti-bacterial wipes			Speaker leads	
Disposable paper towel			Audio connector	
Trolley to hold hardware			Audio splitter	

Table 5.2: Software used for study

Software		
VR Application	**Audio & Vibration**	**Sensor**
bespoke VR experience application (Unity/Android)	Steinberg Cubase LE.	Wild Divine IOM Grapher
		Wild Divine IOM Driver

Chapter 6

User Evaluation

Virtual reality has a unique quality of being able to replicate an experience where the user feels immersed in their environment directly. Situations such as going into the scanner may not be possible to replicate in the physical world due to a number of constraints. VR offers the opportunity for this to be experienced in a virtual environment where the user can have control over the outcomes.

The research questions were posed to investigate whether correlation could be used to predict, pre-procedure, if someone was likely to be able to cope with their MRI brain scan procedure without the need for sedation. The aim being to reduce the number and intensity of sedations administered, reduce cost and bring better health outcomes for patients and health services. Ideally, the VR experience is very close to the real experience and the two are very highly correlated.

The research questions are numbered below and repeated from section 1.1 (where an explanation of the terms can be found):

1. Does exposure have an influence on anxiety?
2. Does stage have an influence on anxiety?
3. Is there an interaction between stage and exposure on anxiety?
4. What is the correlation between anxiety before MRI and during MRI? and
5. What is the correlation between anxiety during VR and during MRI?

6.1 User Experiment Design

This study was a mixed design, with two independent variables (IVs), one between-subject and one within-subject. The first independent variable, VR exposure had two conditions 'yes' or 'no'. The second independent variable is stage with three conditions; 'before' and 'during' or 'after'.

As a health researcher, I want to help MRI staff handling anxious patients booked for an MRI brain scan to determine whether the patient will be able to tolerate their real scan procedure without movement. Therefore, the dependent variable is anxiety level, whilst the within-subjects factor is 'stage' and the between-subjects factor is 'VR exposure'. The two groups reflect the between-subjects factor, the experimental group who have the VR scan (treatment) and the control group who do not. Both groups take their scheduled MRI scan.

In total, 44 participants took part in the experiment. Of these 44 participants, 33 are randomly assigned to undergo VR (experimental) prior to their MRI scan and the remaining 11 to only have their MRI scan (control). Anxiety level is measured at three time points over the scan experience (treatment), which represents the three levels of the 'within-subjects' factor, 'stage' (i.e. anxiety level is measured 'before' [time-point#1], 'during' [time-point#2] and 'after' [time-point#3].

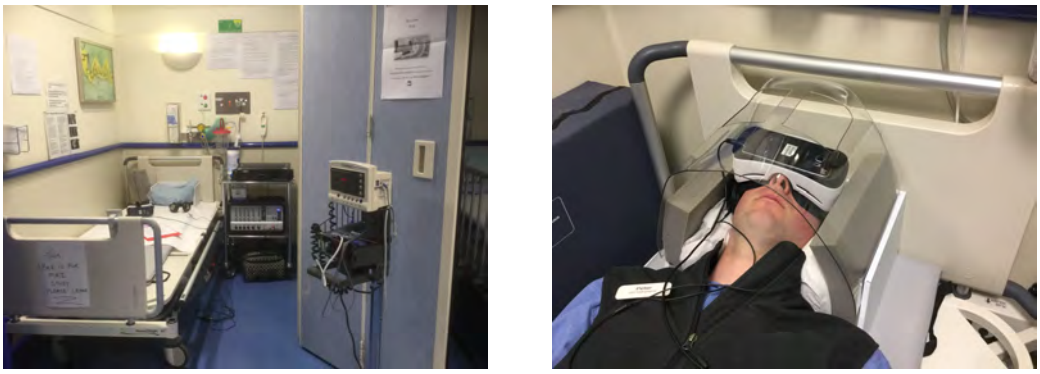
At the end of the experiment, a mixed ANOVA was used to determine whether changes in anxiety level (i.e. the dependent variable) over stage were different for those who undertook VR to those who did not. That is, whether there was an interaction between taking VR ('the between-subjects' factor) and stage (the within-subjects factor). The after measure for state and general anxiety was not necessary to answer the research questions posed and hence was not used in the statistical analysis which used the preferable 'during' measure recorded. As the table 6.1 shows, only two conditions (a, b or c,d) were considered for each experience (VR and MRI), either 'before and during' or 'before and after' (dependent on measure). To illustrate, a: before VR scan, b: during/after VR scan, c: before MRI scan and d: during/after MRI scan. So stage#1 was equal to 'before' (time-point#1), stage#2 was equal to 'during' (time-point#2) or 'after' (time-point#3). Hence, the within-subjects factor only used the first two conditions.

Table 6.1: Mixed Design

	VR scan		MRI scan	
Experimental (VR)	a	b	c	d
Control (No VR)			c	d

6.1.1 Experimental Setup

The study was carried out in an area of radiology services at Christchurch Hospital, Christchurch, NZ. The setup can be seen in Fig. 6.1.



(a) Equipment (b) Patient participant

Figure 6.1: Experimental setup

6.1.2 Stimuli

Stimuli consisted of the virtual reality experience of an MRI scan procedure and the real MRI scan procedure for imaging of the head or shoulder area. Both experiences included the moments of high anxiety identified in van Minde's work of the bed moving into the scanner (van Minde et al., 2014) and

when the scanning noise starts. The procedure used was a head scan which tends to cause higher anxiety (McIsaac, Thordarson, Shafran, Rachman, & Poole, 1998) and (Dewey, Schink, & Dewey, 2007). The VR application gave a 6 minute simulation which included three scanning sequences with sound and vibration lasting between 30 to 45 seconds.The MRI experience lasted the same duration and data gathered. Where this was completed successfully the MRI technician continued to attempt full completion of the required medical procedure outside the confines of this experiment.

6.1.3 Population

Participants were adult patients who have been referred to Canterbury District Health Board for a MRI brain scan within the relevant time period of the study.

To cover legal and ethical matters participants were restricted to those over 18, who needed a brain scan, were able to give consent, well enough to take part and not known to suffer from any symptoms VR is known to induce.

Beforehand, MRI staff had consulted with the patient's referring GP and/or neurologist to check that the medical professional responsible for the patient's care considered the patient suitable to be approached for participation. Only those who are well enough and able to give their verbal or written consent were asked. If patients suffered from seizures or 3D visual impairment they were withdrawn from the study.

If any participant answered the VR consent form positively, the patient was withdrawn from the study.

6.1.4 Experimental Procedure

The hospital user experiment lasted a maximum of 30 minutes. There were two procedures, the experimental group first received a simulated VR MRI scan and then both groups received a MRI scan procedure. This was without intervention for the first ten minutes. If the scan took significantly longer (i.e. 30 minutes) the normal conditions were reverted to and the patient offered music intervention if required. All pre and post measurements were were carried out in the MRI VR cubicle area before entering the scanner room.

The detailed invitation scripts can be found at Appendix D (Experimental Method Detail). On arrival, firstly I worked through the daily set-up sheet (D1.1) to ensure all equipment in the VR cubicle was set up correctly for the day. Then I would check which patients were due to be in that day. In the MRI control room, the whiteboard provided the latest known schedule. Out patients were written up on the whiteboard when their appointment had been confirmed. They were approached on their arrival to the MRI suite using the Out-patient invitation script. For in-patients a morning check was made with the MRI tech for suitable patients coming in to MRI that day (as far as was known) and which ward they were currently on. All scans involving the head and spine were acceptable for study as patients would go in head first wearing the head coil. For each patient the ward was noted and a round prepared to ensure wards were visited as efficiently as possible and rest periods and nurse handovers avoided. Then for each patient, I went up to the ward and looked up the nurse in charge of their care for the current shift. Approaching the nurse concerned, it was checked if they were a suitable participant for the study and well enough to take part. If so and approval had been given to approach, I would visit and invite them to participate in the study using the In-patient invitation script. Offering the forms for signature there and then or for their consideration and call back later at their convenience. In some cases the nurse would refer me to their doctor to consult. This procedure was repeated later in the afternoon for the next day if time permitted.

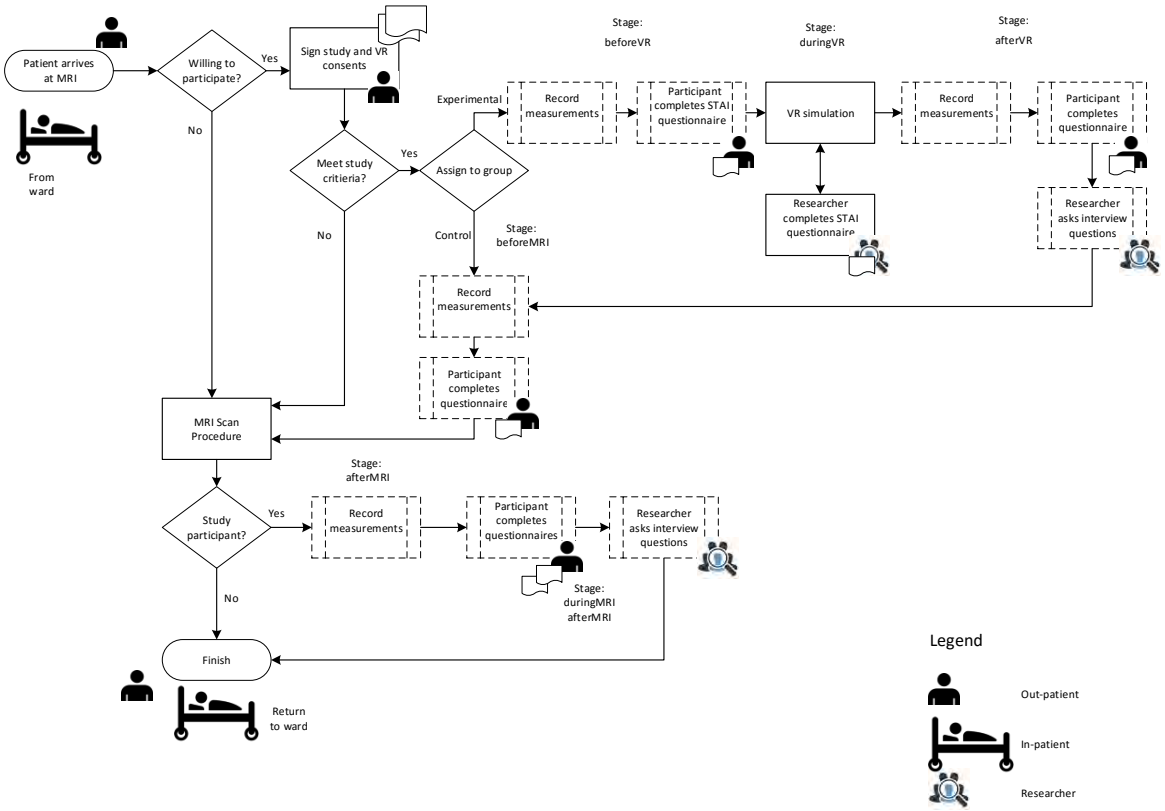


Figure 6.2: Patient participant procedure flow

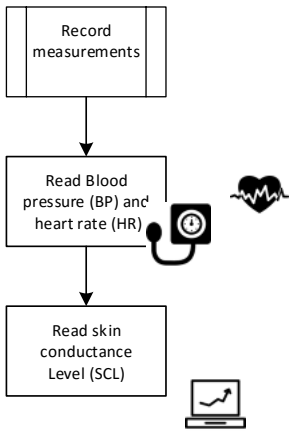


Figure 6.3: Procedure for physiological measurements

For each VR patient a new sheet and pillowcase was made up on the study bed and all equipment wiped with a new antiseptic medical grade wipe before following the daily set-up script for that patient.

The experiment followed the procedure described in the Researcher Script for VR (detailed in Appendix E), overall taking a maximum duration of 30 minutes.

1. At the beginning participants have their blood pressure and heart rate taken. The heart rate clip

is placed on the middle finger on the right hand. The cuff is placed on the participant's left arm just above the elbow and gently wrapped around to secure and the start button pressed on the BP monitor. When it is ready the machine beeps. The systolic and diastolic blood pressure and heart rate are read and manually recorded on the sheet. Then their skin conductance is measured using the IOM blue sensor by slipping the heart sensor clip over the middle left finger and placing the two fingers either side onto the flat disc ski n response sensors. The IOM grapher is used to display the skin conductance values. Read off grapher software and record.

2. They are given a pre-experiment questionnaire to answer, the first of three times. This will be completed for the MRI scan too. The option to have it read out is offered

3. The pre-experiment questionnaire is followed by a detailed briefing of what is going to happen in the experiment which includes the task and process.

4. Participants are settled onto the bed with their legs in front, and provided first with headphones and then the Samsung Gear VR headset and a 'buzzer' squeeze bulb. They are told this equipment replicates what is given when they have their MRI scan.

5. They are invited to explore the MRI room by looking around. They will see the scanner and the MRI tech behind a control window and are told the tech will guide them through. At this point the participant is ready to start the experiment.

6. Participants are told to "Please stay still as movement can spoil the pictures that are being taken by the scanner".You may stop at any time. If you wish to stop just tell me or squeeze this buzzer." They are informed they can be heard but may not hear others so please RAISE YOUR HAND to let us know when you have come out of the scanner."

7. Once they confirm they are ready, the participant is instructed to lie back. On doing so, in the visual application a virtual helmet is placed over the user's face. This coincides with them physically being gently guided back into the neck brace. Then padding is pushed into each side (left first) and the perspex cover pushed home to ensure a snug fit between the padding and pillow and restrict movement.

8. When the participant comes out of the bore the noises stop. The researcher switches off the amplifier, turns the volume on the keyboard down and reads out a repeat of the same questions as before. Responses are manually recorded on the During VR questionnaire by the Researcher.

9. The VR part of the experiment is finished and the head brace is removed by the researcher.

10. The measures are again repeated for blood pressure, heart rate and skin conductance and recorded manually.

11. The same questionnaire is presented a third time for completion followed by some overall questions about the VR experience.

12. Lastly there is a debrief session to clarify any issues, comments or concerns before moving onto the real MRI scan.

6.1.5 Experimental Task

Detailed researcher scripts can be found at Appendix D.

While in the bore of the virtual scanner the participant will receive three different scanning sequences with varying sound levels and vibration patterns. This simulates three common MRI plan sequences. Noises of the bed sliding in and out accompany the visuals.

6.1.6 Measures

The level of anxiety in a patient was recorded using six different measures as shown below:

Table 6.2: Measures used to record patient anxiety level

Measure	Description	Abbr. used	Unit		Range	Example
state anxiety	Pro-rated mean score (20-80) calculated from responses to STAI Y-6 form questionnaire	STAI (sa)	numeric	integer	20-80	23.67
general anxiety	Stage: before or during MRI	GAS (gas)	single integer	integer	1-4	2
heart rate	The speed at which the heart beats	HR (hr)	beats per minute	b.p.m	60-100 (athlete 40)	84
blood pressure	The pressure of the blood in the circulatory system (note: the difference between systolic and diastolic is important, the smaller it is the better for the patient.)	BP (bp)	millimetres of mercury	mmHg	low ideal pre-high high	120/80
systolic blood pressure	Pressure when the heart beats (during contraction)	BPS (sbp)			low 70-90 ideal 90-120 pre-high 120-140 high 140-190	120
diastolic blood pressure	Pressure when the heart is at rest between beats	BPD (dbp)			low 40-60 ideal 60-80 pre-high 80-90 high 90-100	80
skin conductance level	A galvanic skin response (GSR) sensor is used to measure the electrical conductance of the skin, which varies with its moisture level.	SCL scl	micro Siemens or micro Ohms	μS $\mu\Omega$	2-20 (scl) 0.1-1.0 (scr)	2.3 .51

There were six measurement points throughout the experiment; before, during and after VR and before, during and after MRI. This is shown in table 6.3 (using conditions from table 6.1)

Measures using physiological sensors could only be taken before and after each scan procedure as this equipment could not go into the MRI room (conclusion from pilot study in hospital see section 4.4).

Table 6.3: Measurement points (a)

	VR scan			MRI scan		
	Before	During	After	Before	During	After
Control (No VR)				c	d	d
Experimental (VR)	a	b	b	c	d	d

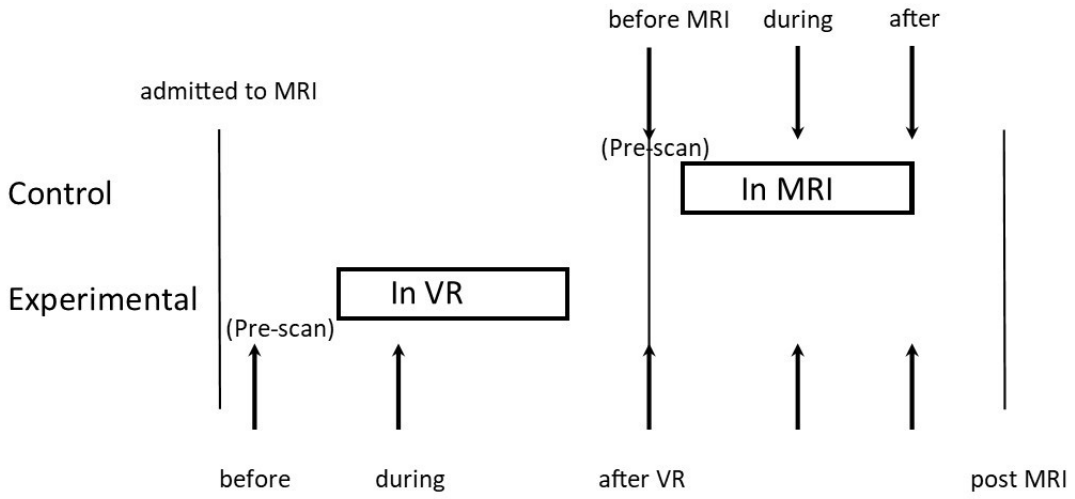


Figure 6.4: Measurement points (b)

Measurements taken after VR were replicated in the data file to complete measurements before MRI. This was because in some cases there was no time to repeat the measurement to ensure MRI appointment times were met, so all data was replicated for uniformity. Figure 6.4 illustrates this. .

All are continuous interval measures. STAI has values from 20 - 80 representing a pro-rated mean score. A score of 20 represents a score of 'not at all anxious' and 80 of 'very much anxious' relating to all questions posed. The physiological measures of anxiety were before and after, for heart rate (beats per minute b.p.m.), blood pressure (systolic rate / diastolic rate) and skin conductance (in micro-siemens) as shown in table 6.2

6.1.7 Operationalisation

If a patient's anxiety level increases, the following table shows that each measure is expected to increase. The same is true for a decrease. So the measures are expected to be consistent.

6.1.8 Measures for research questions 1, 2 and 3

State anxiety reflective of during the VR was used for the experimental group to compare against state anxiety during the real MRI scan. For the control group pre-scan state anxiety was used, (i.e. before the MRI scan). As the result from the six questions was a pro-rated mean score, a parametric test could be used. A two-way mixed ANOVA was used to test group differences.

Table 6.4: Operationalisation of patient anxiety level

Anxiety level +	(increase)		Anxiety level -	(decrease)	
	state anxiety	+		state anxiety	-
	general anxiety	+		general anxiety	-
	heart rate	+		heart rate	-
	blood pressure systolic	+		blood pressure systolic	-
	blood pressure diastolic	+		blood pressure diastolic	-
	skin conductance	+		skin conductance	-

Table 6.5: State anxiety for research question 1, 2 and 3 - two-way mixed ANOVA

Research Question 1	VR scan			MRI scan		
	Before	During	After	Before	During	After
Experimental (VR)		sa			sa	
Control (No VR)				sa	sa	

General anxiety is a likert-scale of 1-4 measured during MRI scan. For this study it will be considered as an interval measure and treated with the same parametric test as state anxiety.

Table 6.6: General anxiety for research question 1, 2 and 3 - two-way mixed ANOVA

Research Question 1	VR scan			MRI scan		
	Before	During	After	Before	During	After
Experimental (VR)		ga			ga	
Control (No VR)				ga	ga	

Heart rate, blood pressure and skin conductance used measurements before and after the MRI scan. An example using heart rate is illustrated below and applicable to all other physiological measures.

Table 6.7: Heart rate for research question 1, 2 and 3 - two-way mixed ANOVA

Research Question 1	VR scan	VR scan	MRI scan	MRI scan
	Before	After	Before	After
Experimental (VR)			hr	hr
Control (No VR)			hr	hr

6.1.9 Measures for Research Question 4

State anxiety measurements taken 'before MRI' and 'during MRI' scan will be used as shown in table 6.8. A new variable 'pre-scan' was created to reference the appropriate before values for each group. For the experimental group, the 'before VR' value will be used and for the control group the 'before MRI' value will be used. The 'during MRI' value will be used for both groups.

Table 6.8: State Anxiety for Research Question 4 - Linear Regression

Research Question 4	VR scan			MRI scan		
	Before	During	After	Before	During	After
Experimental (VR)	sa				sa	
Control (No VR)				sa	sa	

6.1.10 Measures for research question 5

State anxiety measurements taken 'during VR' and 'during MRI' scan will be used as shown in table 6.9.

Table 6.9: State Anxiety for Research Question 5 - Linear Regression

Research Question 5	VR scan			MRI scan		
	Before	During	After	Before	During	After
Experimental (VR)		sa			sa	

6.2 Forms

Hard copy documentation packs were made up for each participant comprising of all scripts and forms for completion. Use of electronic methods for data gathering of patient responses was considered, but pen and paper was favoured for practicality of reading and signing, clarity of what was being recorded and as the most familiar form to the majority of patients, particularly those more senior in years.

6.3 Summary

This chapter described an experiment which uses the created VR system to investigate the effect of a user's exposure to VR on their anxiety during an MRI brain scan. It also investigates whether their anxiety is affected by time stage in relation to the MRI scan procedure and the effect of interaction between exposure to VR and stage. It proposed a mixed design with two independent variables, one between-subject (VR exposure) and one within-subject (stage). It described the experimental setup at Christchurch Hospital. Participants were adult patients scheduled for their scan in the experimental time period and well enough to consent. The procedure is described along with timing of the six measures of anxiety used. These measures are state anxiety, general anxiety, blood pressure (systolic and diastolic) and skin conductance. For the two types of MRI scan, virtual and real; measures are taken at two time points. Self-report measures are taken before and during and physiological measures before and after each scan experience.

Chapter 7

Results

7.1 Data Quality

On data clean up, patient participant 48 was withdrawn because of lack of quality data (for all measures). Participant 6 was uncomfortable in the scan with motion degraded images. The scan was terminated incomplete by the patient after 40 minutes. This patient was therefore withdrawn.

Five patients were withdrawn because they answered positively to questions on the consent form for virtual reality study participants (included at Appendix B). These were the safety questions neurologists advised to be asked to screen their patients for suitability prior to VR. (e.g. Do you suffer from, or have a history of seizures?) These participants were therefore deemed not well enough to take part.

Sample numbers were reduced by data cleansing and withdrawing patients following questionnaire to thirty three experimental and eleven control participants.

This chapter presents the results obtained from the user experiment. The data collected from each patient participant consists of a dialogue sheet, pre-experiment questionnaire, one per condition questionnaire and one post-experiment questionnaire. The pre-experiment questionnaire collected patient participant's demographic information and categorical (nominal) data relating to patient history. The per condition data collected quantitative data repeating the six STAI questions for that specific condition. The post-experiment questionnaire collected quantitative and qualitative data comparing the two experiences and overall experience.

The statistical tests used listwise comparisons so only data where all values are present will be considered (e.g. female participant Id 40 had 'STAI during MRI' value missing and therefore was excluded from the experimental group by the two-way mixed ANOVA when using this (STAI) measure of anxiety level). Note:Laerd has been used for reference to statistical test write-up (Lund, n.d.)[1].

The sample of forty four participants was unbalanced, with thirty three in the experimental group and eleven in the control group.

7.2 Demographics

Recruiting participants from the specific patient pool has proven to be a challenging task. For the user experiment 44 patient volunteers took part, 27 (61 percent) males and 17 (39 percent) females. For

[1]Linear regression and two-way mixed ANOVA `http://statistics.laerd.com` accurate as of 22 July 2017

recording, age was assigned equal categories of nine years from 18-24 to 74-85. Participants covered all ranges with a mean of 38.9 (median of 40) and a standard deviation of 1.646 years.

Nominal information included gender*[2], age*, nationality*, whether the patient has had an MRI before* (19, 43%), heard from others of their experience* (8, 18%), or has a history of anxiety* (11, 25%). Also recorded is whether they were currently taking medication* (and the type) and wore glasses*. 13 (30%) did and an additional 7 (16%) only for reading.

In summary, 15 patients were under 45 (34%) and 29 were 45 years and over (66%)

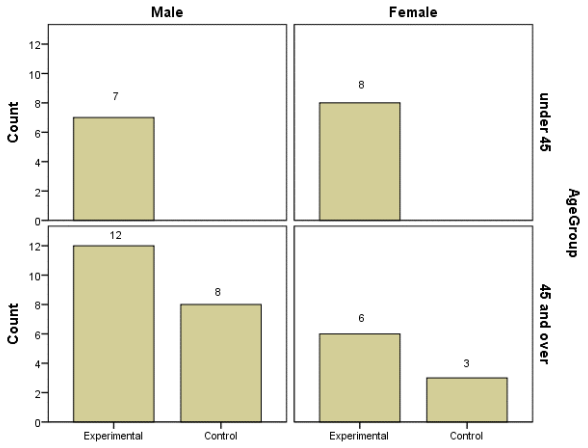


Figure 7.1: Age gender split of patient participants

7.3 Two-way mixed ANOVA - Research Questions 1,2,3

To answer the research questions 1, 2 and 3, a two-way mixed ANOVA was used to investigate the difference in anxiety level measured between groups. There were two designs; the first used self-report measures of state and general anxiety (before and during the MRI scan) and the second used physiological measures of heart rate, blood pressure and skin conductance (before and after the MRI scan).

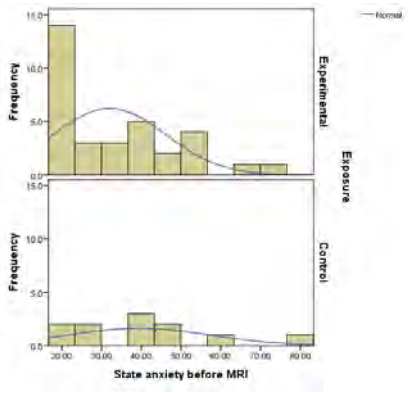
Separate ANOVAs were run to meet the assumption of homogeneity of co-variances (Box's M test p>.05). Results for each measure are given in the following subsections.

7.3.1 Self-Report: State Anxiety

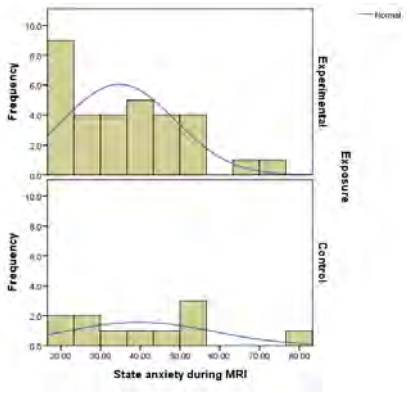
In order to run a two-way mixed ANOVA for the control group the state anxiety before MRI measure has been used and for the experimental group, the state anxiety during VR. State anxiety during MRI has been used for both groups. This has been shown in table 6.5.

For state anxiety the sample was forty three (N=43), with thirty two participants (N=32) in the experimental group and eleven participants (N=11) in the control group. For those who did VR, the mean state anxiety during VR (mean=31.354, SD=11.386) was less than the mean state anxiety in MRI(mean=34.687, SD=14.037). In both mean values the SD was relatively small, with a wider range during MRI. For those who did not do VR, the mean state anxiety before MRI was higher (mean=39.393, SD=18.124)and stayed higher during MRI (39.696, SD=18.647) with a wider range, although their increase in mean value was smaller (+ 0.303) than for those in VR (+3.333).

[2]for simplicity, values with an * (asterisk) have not been used in the results section of this study.



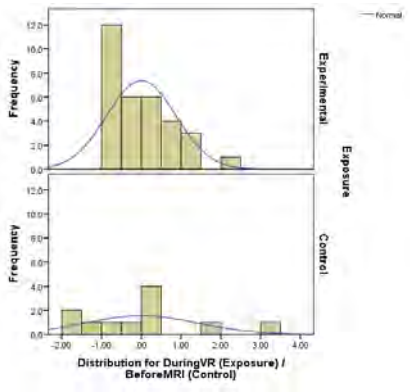
(a) Distribution of state anxiety scores before MRI



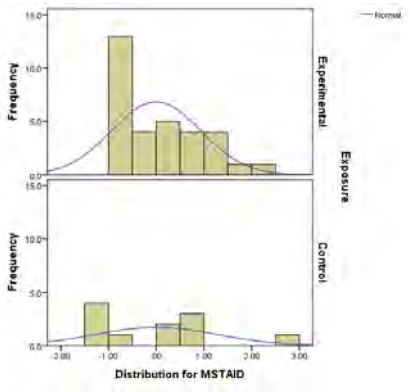
(b) Distributions of state anxiety scores during MRI

Figure 7.2: Histograms showing the distributions of state anxiety scores in the experimental and control groups

Distribution is positively skewed in the sample of those who took the VR experience (see Fig. 7.2). There is a wider spread of scores in the control group.



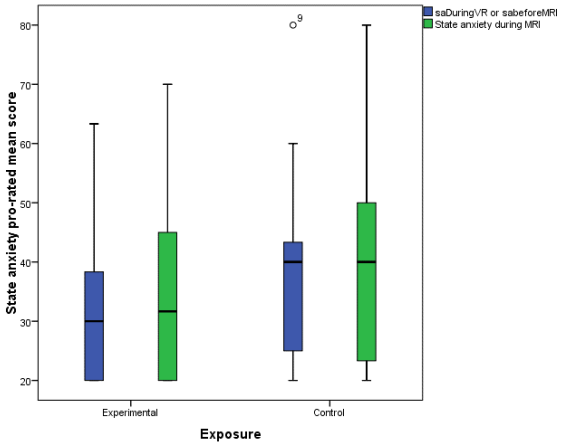
(a) Residuals of state anxiety scores before MRI



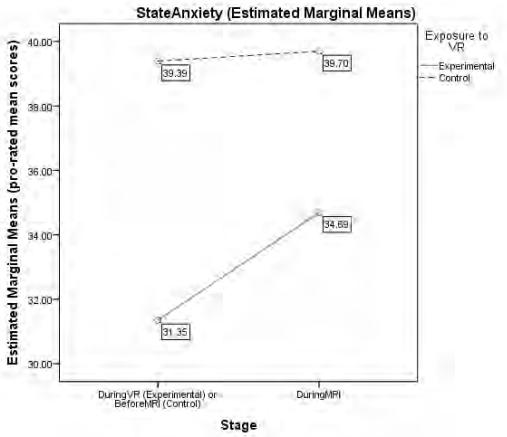
(b) Residuals of state anxiety scores during MRI

Figure 7.3: Histograms showing the residual state anxiety scores in the experimental and control groups

There was one outlier in the data as assessed by inspection of a boxplot for values greater than 1.5 box-lengths from the edge of the box. This outlier for control participant id 9 was retained as it was accurately recorded from the participant. The assumption of normality was violated for both measures in the experimental group when assessed by Shapiro-Wilk test. State anxiety during VR p=.002 and state anxiety during MRI p=.005. For the control group state anxiety was normally distributed, as assessed by Shapiro-Wilk's test (p>.05). As ANOVAs are considered fairly robust to deviations from normality, the approach taken was to carry on regardless as the data was accurately recorded. There was homogeneity of variances (p > .05) and co-variances (p > .05), as assessed by Levene's test of homogeneity of variances and Box's M test, respectively. There was no statistically significant interaction between the intervention and stage on state anxiety, (F1,41) = 1.002, p=.323, $\eta^2 = .024$.The main effect of stage showed there was no statistically significant difference in mean state anxiety at the different time points, F(1,41) = 1.442, p=.237, $\eta^2 = .034$.The main effect of exposure showed there was no statistically significant difference in mean state anxiety between intervention groups F(1,41) = 1.861, p=.180, $\eta^2 = .043$.



(a) Boxplot for state anxiety showing retained outlier for control group



(b) Two-way mixed ANOVA - state anxiety estimated means

Figure 7.4: State anxiety - comparisons of experimental and control group

Table 7.1: State anxiety, two-way repeated measure ANOVA results

Measure	IV's main effect and interaction effect	F(1,41)	Sig.	η^2
state anxiety	Exposure to VR or not	1.861	.180	.043
	Stage: before or during MRI	1.442	.237	.034
	Exposure * Stage	1.002	.323	.024

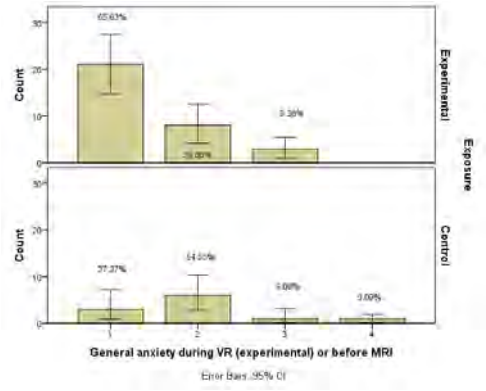
7.3.2 Self-Report: General Anxiety

As with state anxiety, in order to run a two-way mixed ANOVA for the control group the general anxiety score before MRI measure has been used and for the experimental group, the general anxiety during VR measure. General anxiety during MRI measure has been used for both groups.

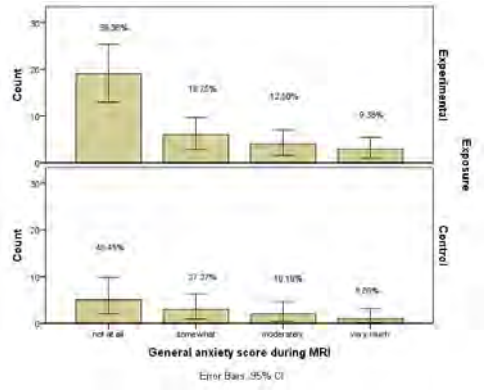
For general anxiety the sample was forty three (N=43), with thirty two participants (N=32) in the experimental group and eleven participants (N=11) in the control group. For those who did VR, the mean general anxiety during VR (mean=1.42, SD=0.661) was slightly less than the mean state anxiety in MRI(mean=1.72, SD=1.023). In both mean values the SD was relatively small, with a wider range during MRI. For those who did not do VR, the mean general anxiety before MRI was higher (mean=2.00, SD=.894)and reduced during MRI (1.91, SD=1.044) with a similar range. Their decrease in mean value of -0.09 compared to an increase for those in VR of +0.3, all values being relatively small, where one was rated as 'not at all anxious' and 2 as 'somewhat anxious' (up to a maximum of four 'very much anxious'.)

During MRI the distributions follow a similar trend, with the experimental group showing a positive skew both in the distribution curve and boxplot.

There were a number of outliers given from the questionnaires. Participant ids 8, 30 and 50 in the experimental group scored maximum of '4' during MRI (very anxious) and one control participant, id=9 scored maximum of '4' before MRI and another, id=7 scored '3' before (moderately anxious). All these values reflected accurately the answers given by participants and was retained for this reason. The data was not normally distributed, as assessed by Shapiro-Wilk's test of normality (not p> .05). For experimental group p=.000 before and during and for control p=.020 and .023 respectively. There was homogeneity of variances (p > .05) and covariances (p > .05), as assessed by Levene's test of homogeneity of variances

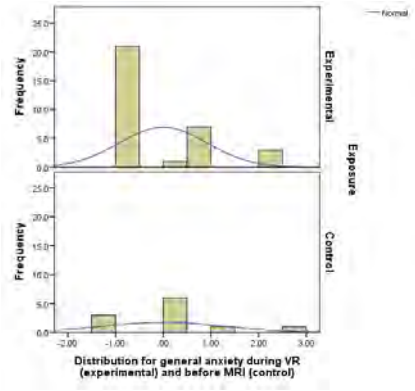


(a) Frequency of general anxiety scores before MRI

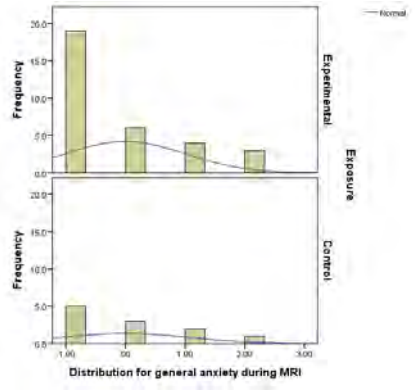


(b) Frequency of general anxiety scores during MRI

Figure 7.5: Bar charts showing general anxiety scores in the experimental and control groups

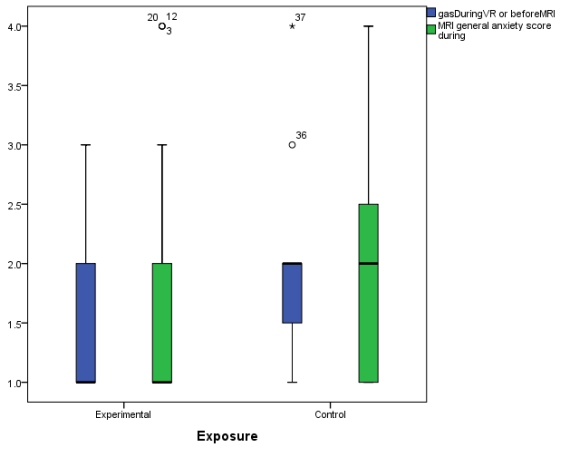


(a) Distribution of general anxiety scores before MRI

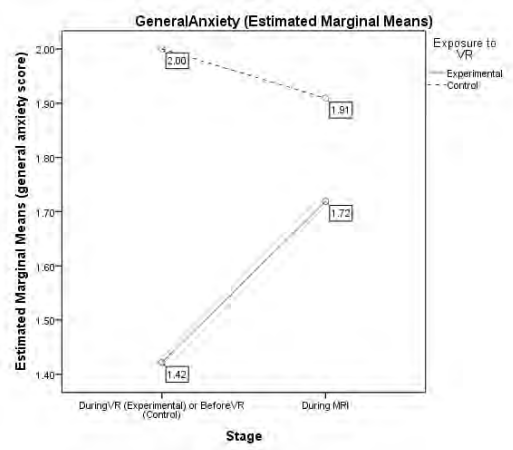


(b) Distribution of general anxiety scores during MRI

Figure 7.6: Distribution of general anxiety in the experimental and control groups



(a) Boxplot for general anxiety showing retained outliers



(b) Two-way mixed ANOVA - general anxiety estimated means

Figure 7.7: General anxiety - comparisons of experimental and control group

and Box's M test, respectively. There was no statistically significant interaction between the intervention and stage on general anxiety F(1,41)=1.916, p=.174, η^2.045. The main effect of stage showed there was no statistically significant difference in mean general anxiety at the different time points, F(1,41)=0.541),

p=.466, η^2.013. The main effect of exposure showed there was no statistically significant difference in mean general anxiety between intervention groups F(1,41)=1.915, p=.174, $\eta^2 = .045$.

Table 7.2: General anxiety, two-way repeated measure ANOVA results

Measure	IV's main effect and interaction effect	F(1,41)	Sig.	η^2
general anxiety	Exposure to VR or not	1.915	.174	.045
	Stage: before or during MRI	0.541	.466	.013
	Exposure * Stage	1.916	.174	.045

7.3.3 Physiological Measures: Heart Rate

All physiological measures (hr, bp and scl) were taken before and after each scan experience. The two-way mixed ANOVA was run for both groups using these measures. Combining the measures brought the sample size down to 30 experimental and 8 control participants respectively as calculations were where values for all measures before and after were present. Considering heart rate separately, only two control cases were omitted giving sample sizes of 33 experimental and 9 control participants.

For anxiety measured by heart rate, the sample was forty two (N=42), with thirty three participants (N=32) in the experimental group and nine participants (N=9) in the control group. For all participants heart rate measured before MRI was higher than the mean heart rate after MRI. For those who did VR their heart rate was lower before MRI (mean=73.73, SD=16.272) than the control group (mean=75.22, SD=12.468) and decreased more (mean=70.21, SD=14.350) than the control (mean=73.56, SD=12.511). A drop of 3.61 b.p.m. for those that had VR compared to a decrease of 1.66 b.p.m. for those who did not.

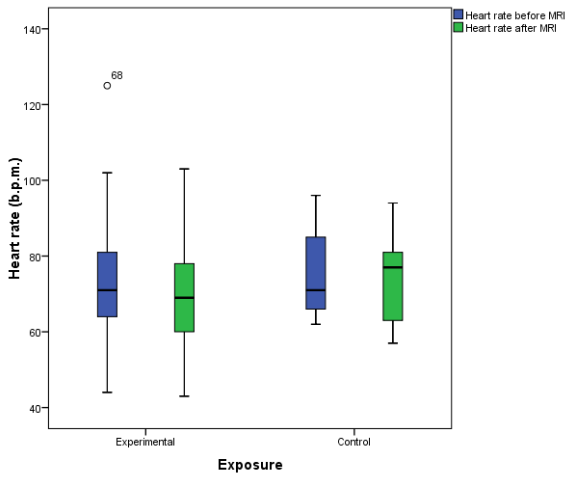


Figure 7.8: Boxplot for heart rate showing retained outliers showing retained outliers for experimental group

The following result is where heart rate was considered separately (for higher statistical power). There was one outlier in the data as assessed by inspection of a boxplot for values greater than 1.5 box-lengths from the edge of the box. This outlier for experimental participant id 68 was retained as it was accurately recorded from the participant. The data was normally distributed, as assessed by Shapiro-Wilk's test of normality (p>.05). There was homogeneity of variances (p>.05) and covariances (p>.05), as assessed by Levene's test of homogeneity of variances and Box's M test, respectively. There was no statistically significant interaction between the intervention and stage on heart rate, F(1,40)=0.481, p=.492, η^2.012.

The main effect of stage showed there was no statistically significant difference in mean heart rate at the different time points, F(1,40)=3.552, p=.067, $\eta^2 = .082$. The main effect of exposure showed that there was no statistically significant difference in heart rate between intervention groups F(1,40)=.209, p=.65, $\eta^2 = .005$.

Table 7.3: Heart rate, two-way repeated measure ANOVA results

Measure	IV's main effect and interaction effect	F(1,40)	Sig.	η^2
heart rate	Exposure to VR or not	0.209	.650	.005
	Stage: before or during MRI	3.552	.067	.082
	Exposure * Stage	0.481	.492	.012

7.3.4 Physiological Measures: Blood pressure - Systolic/Diastolic

Blood pressure is reported as two measures, the systolic (active) heart rate over the diastolic (resting) heart rate and hence both are reported together. For anxiety measured by blood pressure, an increase in anxiety would be represented by an increase in both measures. For simplicity in reporting, in this section each is considered separately.

The sample was forty (N=40), with thirty two participants (N=32) in the experimental group and eight participants (N=8) in the control group. For all participants blood pressure measured before MRI was lower than the blood pressure measured after. In figure 7.9 the graph shows blood pressure

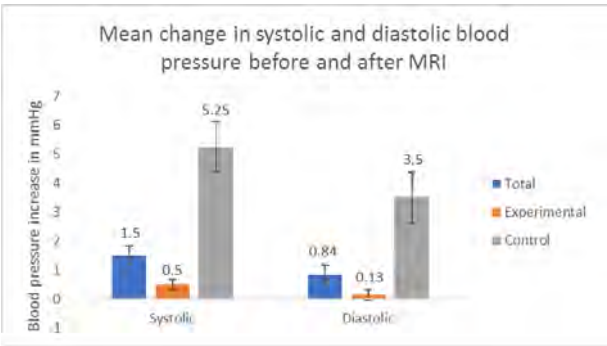


Figure 7.9: Bar chart showing the delta increase in blood pressure after MRI for each group

increased after MRI in both groups. Although not significant, this increase was at a higher level for those in the control group. For those who did VR the average systolic blood pressure was lower before MRI (mean=125.72, SD=16.774) than the control group (mean=127.75, SD=17.442) and increased less (mean=126.00, SD=19.419) than the control (mean=133.00, SD=16.310). Overall systolic blood pressure rose 1.28 mm HG (from mean=126.12, SD16.701 to mean=127.40, SD=18.855). For those who did VR the positive delta was 0.28 mm Hg and for those who did not, the positive delta was 5.25 mm Hg.

For those who did VR the average diastolic blood pressure was higher before MRI (mean=79.00, SD=9.346) than the control group (mean=72.00, SD=6.928) and increased less (mean=79.59, SD=8.191) than the control (mean=75.50, SD=5.345). Overall diastolic blood pressure rose 1.18 mm HG (from mean=77.6, SD9.279 to mean=78.78, SD=7.823). For those who did VR the positive delta was 0.59 mm Hg and for those who did not, the positive delta was 3.5 mm Hg.

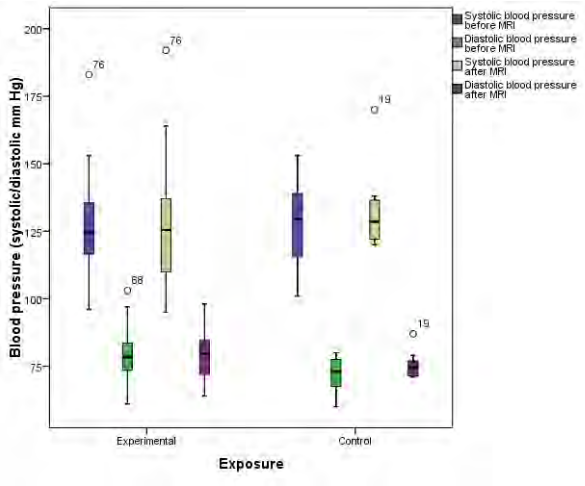


Figure 7.10: Boxplot: blood pressure with retained outliers in both groups

For the systolic blood pressure measure, there were 2 outliers, as assessed by boxplot. Experimental participants 76 and control participant 19 were retained as the values were accurate as recorded. The assumption of normality was violated, as assessed by Shapiro=Wilk's test of normality (p<.05). Systolic blood pressure before MRI (control) was normally distributed (p>.05). There was homogeneity of variances (p > .05) and co-variances (p > .05), as assessed by Levene's test of homogeneity of variances and Box's M test, respectively.There was no statistically significant interaction between the intervention and stage on systolic blood pressure. F(1,38)=1.405, p=.243, $\eta^2 = .036$. The main effect of stage showed a statistically significant difference in mean systolic blood pressure F(1,38)=1.741, p=.195, $\eta^2.044$. The main effect of exposure showed that there was no statistically significant difference in mean systolic blood pressure between intervention groups F(1,38)=0.445, p=.509, $\eta^2 =, 012$.

Table 7.4: Systolic blood pressure, two-way repeated measure ANOVA results

Measure	IV's main effect and interaction effect	F(1,38)	Sig.	η^2
systolic blood pressure	Exposure to VR or not	0.445	.509	.012
	Stage: before or during MRI	1.741	.195	.044
	Exposure * Stage	1.405	.243	.036

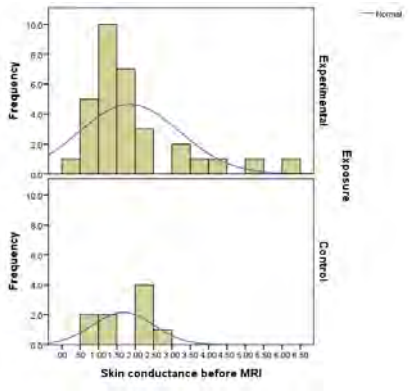
For the diastolic blood pressure measure, there were 2 outliers, as assessed by boxplot. Experimental participant 68 and control participant 19 were retained as the values were accurate as recorded. The assumption of normality was violated, as assessed by Shapiro=Wilk's test of normality (p<.05). Diastolic blood pressure in both groups before MRI and experimental group after MRI were normally distributed (p>.05). There was homogeneity of variances (p > .05) and co-variances (p > .05), as assessed by Levene's test of homogeneity of variances and Box's M test, respectively.There was no statistically significant interaction between the intervention and stage on diastolic blood pressure F(1,38)=1.009, p=.321, $\eta^2 = .026$. The main effect of stage showed no statistically significant difference in mean diastolic blood pressure F(1,38)=2.002, p=.165 $\eta^2.050$. The main effect of exposure showed that there was no statistically significant difference in mean diastolic blood pressure between intervention groups F(1,38)=3.476, p=.070, $\eta^2 = .084$.

Table 7.5: Diastolic blood pressure, two-way repeated measure ANOVA results

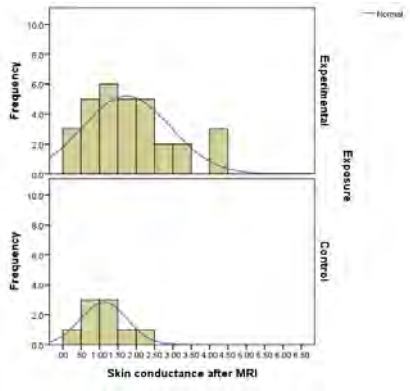
Measure	IV's main effect and interaction effect	F(1,38)	Sig.	η^2
diastolic blood pressure	Exposure to VR or not	3.476	.070	.084
	Stage: before or during MRI	2.002	.165	.050
	Exposure * Stage	1.009	.321	.026

7.3.5 Physiological Measures: Skin conductance

For anxiety measured by skin conductance, the sample was forty (N=40), with thirty one participants (N=31) in the experimental group and nine participants (N=9) in the control group. For all participants skin conductance measured before MRI was higher than the mean skin conductance after MRI. For those who did VR their skin conductance was slightly higher before MRI (mean=1.87, SD=1.394) than the control group (mean=1.67, SD=0.830) and decreased less (mean=1.74, SD=1.189) than the control (mean=1.11, SD=0.631). Overall average skin conductance decreased slightly (from a mean=1.82, SD 1.282 to mean=1.60, SD=1.113).



(a) Distribution of skin conductance (microS) before MRI



(b) Distributions of skin conductance (microS) after MRI

Figure 7.11: Histograms showing the skin conductance in the experimental and control groups

There were four outliers in the experimental group before MRI, participants 20, 72, 78 and 62. There was homogeneity of variances (p > .05) and covariances (p > .05), as assessed by Levene's test of homogeneity of variances and Box's M test, respectively. There was no statistically significant interaction between the intervention and stage on skin conductance level F(1,38)=0.966, p=.332, $\eta^2 = .025$. The main effect of stage showed no statistically significant difference in mean skin conductance F(1,38)=2.468, p=.125, $\eta^2 = .061$. The main effect of exposure showed that there was a no statistically significant difference in mean skin conductance F(1,38)=1.045, p=.313, $\eta^2 = .027$.

Table 7.6: Skin conductance, two-way repeated measure ANOVA results

Measure	IV's main effect and interaction effect	F(1,38)	Sig.	η^2
skin conductance	Exposure to VR or not	1.045	.313	.027
	Stage: before or during MRI	2.468	.125	.061
	Exposure * Stage	.966	.332	.025

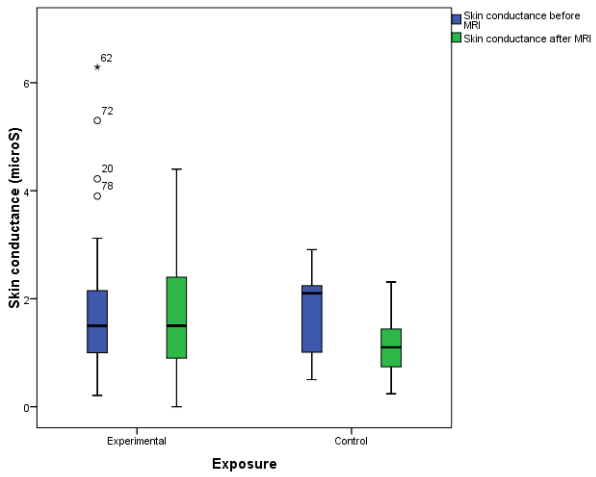


Figure 7.12: Boxplot: skin conductance with retained outliers (experimental group)

7.4 Linear regression - Research Question 4

As the results from the earlier section did not show an interaction between exposure to VR and stage of MRI experience, the design was folded to remove the IV of VR exposure. Thus the question arose; What is the correlation between anxiety level before and during an MRI scan? and subsequently Is anxiety before, useful in predicting anxiety during an MRI brain scan?

This met a study design to determine how much of the variation in anxiety level during MRI can be explained by the anxiety level before MRI and onto prediction of potential anxiety prior to medical procedure. The independent variable was anxiety level before MRI and the dependent variable; anxiety level during MRI. Of the two measures available for anxiety during MRI (general and state), the measure of state anxiety (pro-rated mean score) meets the first two assumptions for linear regression of continuous independent and dependent variables.

For the before MRI variable; a new 'pre-scan state anxiety' variable was created.

7.4.1 Independent variable of pre-scan state anxiety

Pre-scan state anxiety used values of the field VSTAIB (before VR) for the experimental group and MSTAIB (before MRI) for the control group. The common variable state anxiety during MRI (MSTAID) was used for both groups.

The sample was forty three patient participants (N=43). The mean state anxiety before scan (mean=35.659, SD=14.338) increased marginally (mean=35.969, SD=15.268) during MRI (with a little wider range).

Table 7.7: State anxiety descriptive statistics summary

	N	Mean	SD
pre-scan state anxiety	43	35.659	14.338
state anxiety during MRI	43	35.969	15.268

Linearity was established by visual inspection of a scatterplot. There was independence of residuals, as assessed by a Durbin-Watson statistic of 1.994. A linear regression was run to understand the effect

of average state anxiety before MRI on state anxiety during MRI. To assess linearity a scatterplot of state anxiety during MRI against average state anxiety before MRI with superimposed regression line was plotted. Visual inspection of these two plots indicated a linear relationship between the variables. There was homoscedasticity and normality of residuals. One participant, (id=9) was an outlier with a state anxiety during MRI value of '80'. They remained as their reading was accurate to their response and represented a valid value from the target population.

A Pearson's product-moment correlation showed there was a strong positive correlation between pre-scan state anxiety and state anxiety during MRI $r(41) = .767, p < .0005$.

Table 7.8: Pearson correlation for anxiety level pre-scan (IV)

	pre-scan state anxiety	Sig.
state anxiety during MRI	.767	.000

Average state anxiety before MRI statistically significantly predicted state anxiety during MRI, F(1,41)=58.406, P<.001. The prediction equation was:

$$anxiety\,level\,during\,MRI\,scan = 6.863 + (0.816 * anxiety\,level\,before\,MRI\,scan) \tag{7.1}$$

or specifically for the state anxiety measure:

$$state\,anxiety\,during\,MRI = 6.863 + (0.816 * pre-scan\,state\,anxiety\,) \tag{7.2}$$

Average pre-scan state anxiety accounted for 58.8% of the variation in state anxiety during MRI with $adjusted R^2$=57.7%, a medium effect size according to Cohen (1988).

Table 7.9: State anxiety linear regression results (IV: pre-scan)

IV	N	F	(df)	R^2	$adjusted$ R^2	b_0	b_1	Sig.
pre-scan state anxiety	43	58.406	(1,41)	.588	.577	6.863	.816	.000

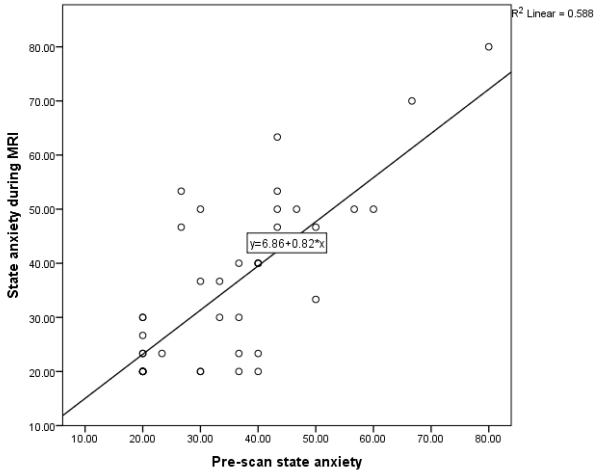


Figure 7.13: Scatterplot showing prediction equation for anxiety level using pre-scan state anxiety

7.5 Linear regression - Question 5

7.5.1 Independent variable of state anxiety during VR

The research question posed "What is the correlation between anxiety during VR and during MRI?" and subsequently "Is VR useful in predicting anxiety of patients during MRI?".

To answer this, the same statistical test of linear regression was run to understand the effect of state anxiety during VR on state anxiety during the real MRI with only experimental group participants.

The sample was thirty two participants (N=32) in the experimental group. The mean state anxiety during VR (mean=31.354, SD=11.386) was less than the mean state anxiety in MRI(mean=34.687, SD=14.037). In both mean values the SD was relatively small, with a wider range during MRI.

Table 7.10: State anxiety descriptive statistics summary (experimental group)

	N	Mean	SD
state anxiety during VR (IV)	32	31.354	11.386
state anxiety during MRI	32	34.687	14.037

To assess linearity, a scatter-plot of state anxiety during MRI against state anxiety during VR with superimposed regression line was plotted. Visual inspection of these two plots indicated a linear relationship between variables (7.14. There was independence of residuals, as assessed by a Durbin-Watson statistic of 2.090. There was homoscedasticity and normality of the residuals (with some kurtosis). One participant (id 44) was an outlier with a state anxiety during MRI of 70. They remained as their reading was accurate to their response and represented a valid value from the target population.

A Pearson's product-moment correlation showed there was a strong positive correlation between state anxiety during VR and state anxiety during MRI $r(30) = .845, p < .0005$.

Table 7.11: Pearson correlation for anxiety level during VR (IV)

	state anxiety during VR	Sig.
state anxiety during MRI	.845	.000

The prediction equation was:

$$anxiety\,level\,during\,MRI\,scan = 2.033 + (1.041 * anxiety\,level\,during\,VRscan) \tag{7.3}$$

or specifically for the state anxiety measure:

$$state\,anxiety\,during\,MRI = 2.033 + (1.041 * state\,anxiety\,during\,VR) \tag{7.4}$$

Average state anxiety during VR statistically significantly predicted state anxiety during MRI, F(1,30) = 74.771 p<.001, accounting for 71.4% of the variation in state anxiety MRI with $adjusted\ R^2 = 70.4\%$, a medium size effect according to Cohen (1988)(as it is less than 0.8).

As a correlation was found, this led to a final question comparing the correlations: How does the correlation between anxiety before and during MRI compare to the correlation between during VR and MRI?

Looking at the Pearson correlation values r, both are considered strong and statistically significant with the during VR value a little higher at .845 compared to pre-scan state anxiety at .767. Both significantly

Table 7.12: State anxiety linear regression results (IV: during VR)

IV	N	F	(df)	R^2	$adjusted\ R^2$	b_0	b_1	Sig.
state anxiety during VR	32	74.771	(1,30)	.714	.704	2.033	1.041	.000

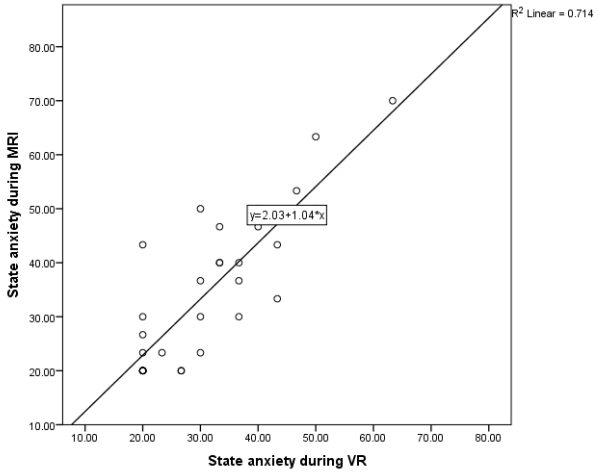


Figure 7.14: Scatterplot showing prediction equation for anxiety level using state anxiety during VR

predicted average state anxiety during MRI, with average state anxiety during VR accounting for 71.4% of state anxiety during MRI of which 58.8 could be predicted by the average state anxiety pre-scan.

7.6 Post-experiment Questionnaire

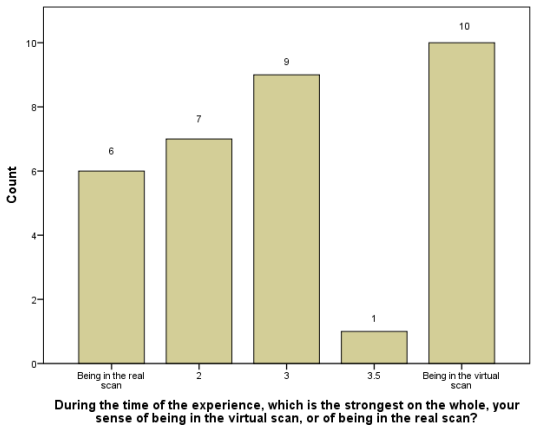
After completing the VR condition, users in the experimental group were asked for their feedback on the VR experience with two questions regarding their sense of presence. Appendix G gives question detail.

Using a four point Likert-scale, users were asked to rate their sense of presence from 1:being in the real scan to 4:being in the virtual scan. ("During the time of the experience, which is the strongest on the whole, your sense of being in the virtual scan, or of being in the real scan?") Figure 7.15a illustrates the response to this question.

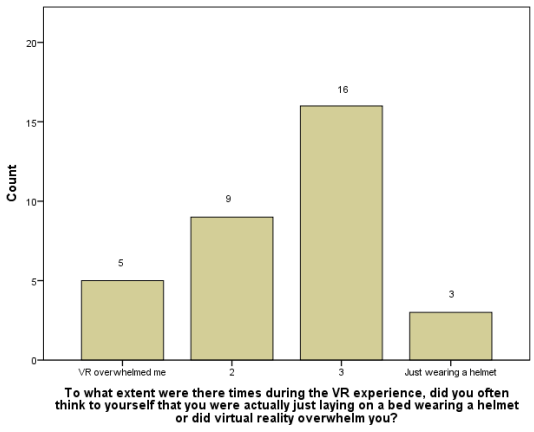
Of the thirty three participants, ten (30%) felt their strongest sense of being was in the virtual scan (scoring a 4). One scored mid-way at 3.5 (despite this not being a category). Nine (27%) scored a 3 and seven (21%) a 2. Six(18%) felt strongest that they were in the real scan. Figure 7.15a shows this as a bar chart.

Experimental users were also asked to what extent they thought to themselves 1:VR overwhelmed me to I'm.. 4:Just wearing a helmet. ("To what extent were there times during the VR experiences, did you often think to yourself that you were actually just laying on a bed wearing a helmet or did virtual reality overwhelm you?") The response is illustrated in 7.15b. Most users responded somewhere in the middle with nine(27%) scoring a 2 and the majority of sixteen (48.5%) scoring a 3. Definitively, three (9%) scored a four (I'm "just wearing a helmet") and the remaining five (15%) felt "VR overwhelmed them".

After completing the MRI scan, users were asked how their anxiety level from VR reflected their real MRI experience ("How did your anxiety level from the VR experience reflect the real MRI experience?")



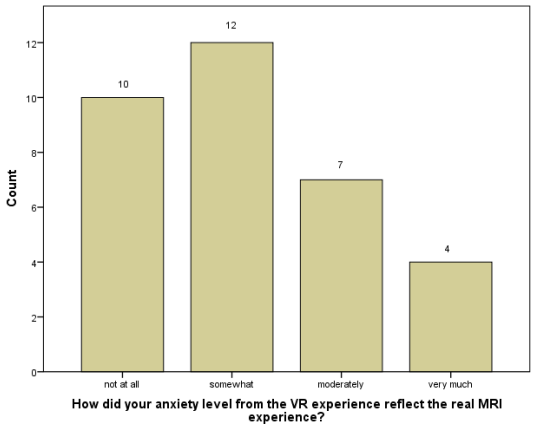
(a) Q1: Real or virtual scan?



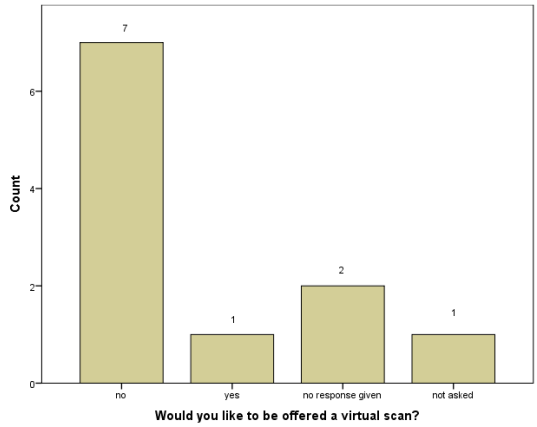
(b) Q2: Overwhelmed by VR?

Figure 7.15: Experimental group responses for sense of presence in VR

Again users were presented with a four point Likert-scale from 1:not at all to 4:very much. The bar chart in figure 7.16a shows the ranking. Ten rated (30%) "not at all", the majority of 12 (36%) "somewhat", seven (21%) "moderately" and the remaining four (12%) "very much".



(a) Q3: Experimental - How did your anxiety reflect the real MRI scan?



(b) Q4: Control- Would you like VR?

Figure 7.16: Overall participant responses

Both VR and MRI questionnaires invited participants to make further comments (see next section; Qualitative Results).

On their questionnaire, the control group were asked one question, if they would they like to be offered a virtual scan and invited to offer further comments. As figure 7.16b shows, one participant (9%) answered yes they would like to be offered a virtual scan, and seven(64%) answered no they did not. Two participants (18%) left this question blank and two (18%) were not asked due to an error in process (their back page of the questionnaire was blank).

7.7 Qualitative Results

This section deals with the further comments given in the post-experiment questionnaires.

7.7.1 Experimental Group

Of the thirty four participants, twenty two (65%) commented on the VR and twenty eight(82%) commented on MRI.

Eight (40%) of the participants who commented found the VR experience fun and exciting, and were happy to have been chosen to try it. Four (20%) of the participants mentioned that the VR experience was very similar to the actual MRI. However, eight (40%) of the participants felt that there were some differences, which 3 (15%) participants attributed to the prototype having poor graphics. Four (20%) of the participants felt that the main difference between the MRI and VR experience was that the MRI space felt spatially smaller, tighter, and they were aware of the need to stay still whilst they were sliding into the tube. One (5%) participant also mentioned that the actual MRI scan had more vibrations than the VR. Two participants (10%) felt that they were not aware of wearing a helmet in the VR experience, this could be because the helmet was not tight enough, or because they were too immersed in the VR environment.

Five (55%) of the participants who were naïve to MRI scans and 6 (54%) of the experienced participants felt that VR would be very useful in helping patients prepare for the actual MRI scans. However, 1 of the naïve participants mentioned that the VR did not make much difference for him. This could be because he did not have much anxiety for the actual MRI scan.

A few suggestions that participants provided as part of the qualitative feedback included increasing the feeling of tightness or adding cushions in the VR experience to further simulate the MRI experience, increasing the noise and movements in the VR experience, and improving the graphics quality to be look more natural.

Details of all responses are given in Appendix H -Qualitative section. Those of particular interest have been noted below. The experience the quote related to is shown in brackets after it, i.e. (MRI) or (VR).

"At one point it was hard to swallow - thought 'I'm not pressing that button'. Think it was the weight of that thing on my chest as you are breathing - thinking it was that. A little bit different to the virtual one, more enclosed, but it was just a feeling. Can feel your arms sliding through the tube - a bit tighter. It's spatial. The room seemed a lot bigger in VR and no sliding. "Pleased you did the virtual reality - it's been the highlight of my day".(MRI) (Id 4)

"That was quite fun - definitely a different way of doing an MRI."(VR) "When I was in the MRI there wasn't really much difference. Offering VR first - I think it's a good idea. Gives people an opportunity to see and also being aware of what of what they're going into."(MRI) (Id 24)

"It was out there - cool - a wow factor.(VR)" "Be prepared hot and sweaty" Got locked in a boot once - it was freaky, couldn't get out. In the MRI, I made myself stay in the scanner because I want to know what's wrong with me. If I didn't have the box over my head I would have been alright.(MRI)" Patient had MRI spine imaging with headpiece. (Id 36)

"The virtual test prepares you for the real test, so I feel the virtual test makes you calmer for the real test. It could be useful for children to see how they will be"(MRI) (Id 46)

"The only time I was aware of wearing a helmet was when Helen was adjusting the head VR helpful to be prepared for noise, closeness to machine, possibility of mirror and enable communication with MRI tech.. for me. Cool - very good. It felt like a natural feeling that you are there."(VR) VR helpful to be prepared for noise, closeness to machine, possibility of mirror and enable communication with MRI tech..(MRI) Id(50)

"I found it absolutely marvellous – it was like a wee adventure."(VR) ... "VR was great prep for MRI = No surprises. Great Experience"(MRI) (Id 53)

"Ambivalent about benefit. When asked whether he would want to be offered VR in the future, the patient replied, ""It prepared me slightly - but I don't know if it is worth the time for patients and support staff. Though the graphics were bad, I felt, taking the headset off... I was surprised to be in a different place."(VR) "I was very slightly claustrophobic during the real MRI only. I was aware of a need to stay still. The real MRI was of much longer duration. Comparing the two I found: ""MRI distressing"", I had to ""lie still"" for the ""duration"" and was ""aware of being in a tube"" whereas the VR was ""brief"", I ""knew it wasn't enclosed, there was no consequence to moving"" and I ""knew i could sit up""."(MRI)(Id 66)

"Felt like I was in a massive room. Unreal. It was incredible."(VR)
"VR is very similar to MRI"(MRI) (Id 74)

"I was the anomaly because I am never relaxed. I had no anxiety. I shake (due to medication / Parkinsons). It'd be quite useful for their first time, when you have no expectation. When you don't know what to think, especially with children, can be quite daunting."(VR) "Useful to first time patients"(MRI) (Id 76)

"It's like being in the real scan but not. Gets you ready for the real scan."(VR) (Id 94)

Christchurch Hospital asked if they could use two of these cases in their patient stories advertising. This research gives an indication to warrant further investment in research due to the potential cost-benefit analysis of implementing such an intervention in the hospital.

7.7.2 Control Group

Of the eleven control group participants, two (18%) gave further comments.

"I remember my first MRI - I WAS somewhat frightened. This is my third MRI - much easier." (MRI) (Id 13)

"Engaging in the process itself ...is lowering the anxiety. Self anxiety indicator is a stutter. My anxiety is eased by information. My anxiety was reduced by everybody's professionalism. At the same time their friendliness, caring attitude, respect and use of first names."(MRI) (Id 19)

7.8 Summary

The sample of forty four patients comprised of 27 (61%) males and 17 (39%) females, with a median age of 40 and a standard deviation of 14.8 years. To answer the first three research questions posed, a two-way mixed ANOVA was run. The overall anxiety level data showed that there was no statistically significant interaction between the VR intervention and stage on anxiety level (p>.05). The main effect of exposure showed that there was no statistically significant difference in anxiety level between those who had VR and those who did not. The main effect of stage showed there was no statistically significant difference n mean anxiety level at the different time points of the scan. This chapter dealt with each of the six measures in turn; state anxiety, general anxiety, heart rate, blood pressure (systolic and diastolic) and skin conductance with these same findings presented.

Folding the design to remove VR, linear regression analysis was run to test if anxiety before scan, significantly predicted patient's anxiety during MRI. The results of the regression indicated the predictor explained 58.8% of the variance. It was found that patient anxiety before scan, significantly predicted patient anxiety during MRI. Anxiety level and stage were significantly correlated (R=.767, p<.001). For the experimental group, a linear regression analysis was repeated to test if anxiety during VR significantly predicted patient's anxiety during MRI. It was found that patient anxiety during VR significantly predicted patient anxiety during MRI. Anxiety level and exposure to VR were significantly correlated.(R=.845, p<.001). Comparing the two correlations, both are considered strong and statistically significant with the during VR value a little higher. Both significantly predicted average state anxiety during MRI, with average state anxiety during VR accounting for 71.4% of state anxiety during MRI of which 58.8 could be predicted by the average state anxiety pre-scan.

For VR participants, analysis of the post-experiment questionnaire gave user response regarding their sense of presence and to what extent they found themselves overwhelmed by virtual reality. Also how their anxiety level from the VR experience reflected the real MRI scan. Non-VR participants were asked if they would like to be offered a virtual scan. Lastly, qualitative results were documented in the form of comments received and their groupings with 82% of VR participants and 18% of non-VR participants commenting. The next chapter gives a discussion of these results.

Chapter 8

Discussion

This chapter firstly looks at the problem posed by Christchurch Hospital and then discusses the results found in the user study. It considers the answers to the research questions, explores possible explanations of the results and implications with previous work. Finally it covers limitations of the study and gives recommendations for further work. For ease of referencing, recommendations have been tagged with 'R' and numbered.

8.1 Patient Anxiety Threshold

Initially the experiment set out to show at what threshold truly scared patients would prematurely end their MRI procedure. This was required to determine at the highest level whether good quality images were likely to be obtained from the real scan. However, all patients resulted in good quality images so the binary variables to be measured were constant and gave no further information and hence no relevance. Without a proportion of participants terminating early, the experiment at the highest level failed to observe the anxiety threshold at which patients would terminate their MRI scan procedure. The most likely reason for this may be that those who took part chose to do so. This raised an internal integrity concern of strong self-selection bias with the most anxious patients just not willing to engage in the study. However ethics have clearly stated the necessity for voluntary participation so recommendations given later in this chapter take this into account. (See Recommendation R1)

8.2 Study Results

The points at which anxiety measurements have been taken is illustrated in figure 6.3. There were three stages in each scan experience, before, during and after. State and general anxiety were measured at all three points. Only two measures were required for each statistical test, usually before and during. This was not possible for the physiological measures which could not be taken during the MRI scan experience so they were recorded before and after. Values used for pre-scan data are before VR and before MRI for experimental and control participants respectively. Definitions of the terms (anxiety, exposure and stage) can be found in section 1.1. Each of the research questions were considered in turn. For the first three questions, findings were consistent across all six measures of anxiety level recorded (self report measures of state anxiety, general anxiety and physiological measures of heart rate, blood pressure and skin conductance). A table summarising the findings can be seen in 8.1.

Table 8.1: Research Questions 1-3 results

	Research Question	Result		Sig.
1.	Does exposure have an influence on anxiety?	No significance found	p>.05	.180
2.	Does stage have an influence on anxiety?	No significance found	p>.05	.237
3.	Is there an interaction between stage and exposure?	No significance found	p>.05	.323

8.2.1 Does exposure have an influence on anxiety? (Q1)

No statistically significant difference was found in patient's mean anxiety level during MRI between those who had had the VR simulation before their MRI scan and those who had not. Therefore our results did not show exposure (to VR) had an influence on patient anxiety.

8.2.2 Does stage have an influence on anxiety? (Q2)

No statistically significant difference was found in patient's mean anxiety level during MRI between the different time points of the scan. Therefore our results did not show stage (of MRI scan) had an influence on anxiety. This finding was consistent across all six measures of anxiety recorded.

8.2.3 Is there an interaction between stage and exposure? (Q3)

No statistically significant interaction was found between the intervention and time point within the MRI scan. Hence, our results did not show an interaction between stage and exposure. This finding was consistent across all six measure of anxiety recorded.

8.2.4 What is the correlation between anxiety before and during? (Q4)

Combining both groups, for all forty three participants (N=43) there was a large positive correlation between the anxiety level measured after arrival in the MRI suite (pre-scan) and anxiety level during the MRI brain scan.

8.2.5 How does this compare to the correlation during VR? (Q5)

Considering the experimental group only, for the thirty two participants (N=32) there was a stronger positive correlation between the anxiety level measured during VR and the anxiety level during the MRI brain scan (r =.845) as opposed to that measured pre-scan (r =.767). Both were significant at $p < .0005$.

Table 8.2: Research Questions 4 and 5 results

	Research Question	Result	$adjusted$ R^2	b_1	b_0	Sig. p>.05
4.	What is the correlation between anxiety before and during?	Correlation found	57.7%	6.863	0.816	.000
5.	How does this compare to the correlation during VR?	Correlation found	70.4%	2.033	1.041	.000

8.2.6 What does this mean for our study?

Statistical results from group differences of anxiety yielded no significance across the first three research questions and prompted folding of the experiment to remove the effect of VR. Investigation of the means of state anxiety showed anxiety of patients in the experimental group was lower before MRI and remained lower during MRI than the control group , although not statistically significantly so. Figure 7.4b illustrates this.

Investigating 'stage' further, the strong positive correlation found ($r = 7.67, p < .0005$) has shown that given a patient's state anxiety score pre-scan, their score during the MRI can be predicted. This holds promise for further action in the hospital as detailed in recommendations section of this chapter.

8.3 Population

All patients presented at Christchurch Hospital. The population for this experiment was identified as those well enough to be approached to take part when the researcher was present at the MRI suite in Christchurch Hospital. In general the Researcher was available in 2016 for a continuous period from 26 August through to 29 September, plus two scheduled weekend sessions in October 2016 (15-16 and 22-23). This period excluded the three slots each Tuesday and Thursday reserved for patients sedated under GA. From the population of one hundred and thirteen who were scheduled for head scans over this time, thirty four (30%) were not approached due to a number of factors including requiring sedation, unable to give consent, or not being well enough. A further four (3.5%) did not attend their appointment. Of those approached, fourteen (12%) declined to take part. Ten (8.9%) who gave consent were later withdrawn on medical grounds including one patient whose scan was cancelled as the patient was not well enough to undertake it.

This left fifty participants. Presentation of the consent form for virtual reality identified five further cases (6%) where willing participants were found to be unsuitable and therefore withdrawn. So the sample of forty four participants comprised 38.9% of the original population. Thirty three first had the virtual experience before their MRI and eleven had only the MRI scan.

8.3.1 Interesting Participant Cases

Of the participants who were approached, one decided not to take part, and did not successfully complete their scan. They were also unsuccessful with sedation, leaving the scan bed during the procedure to lay down in the lobby and promptly fall asleep.

Two patients, accompanied by a nurse, had been transferred from another hospital, outside the District Health Board. Both patients declined to take part. In this instance, their nurse was not approached individually beforehand, though voiced that if there had been the opportunity, it would have been recommended to ask the second patient separately who would not then have been influenced by the first who had a psychiatric disorder and would not have been recommended to approach.

One patient was withdrawn due to supervisory requirements, which made taking part impractical.

Another patient was more stressed due to substance dependence which added to the discomfort felt during the real scan. The patient was kept in the study since they were representative of those in the desired population.

One was unable to remember the VR procedure and was withdrawn (id=6). For another, it was questioned whether they were well enough to take part and their results have been ignored (id 35).

In one case (id 18) an experimental patient was given music (after 10 minutes due to the patient needing significantly longer in the scanner).

Process error led to five patients not having results recorded (id's 2,4,12,16 and 40) and one patient's withdrawal due to lack of MRI data (id=48).

8.3.2 Population Findings

Initially of those approached, there were more males accepting to take part (thirty one (60%) males and twenty one (40% females). Nine females (64%) and five(36%) males declined. There was also a noticeable absence of females in the older age groups who took part (three (27%) females and eight (73%) males. This is in line with Munn's findings (Munn, Moola, et al., 2015). The majority of those who declined gave a reason linked to their own anxiety and some gave no reason. So at the first step, the desired audience did not engage with the experiment. (R1)

Of those who did choose to take part, when sorted the population of males and females were fairly well distributed through the range of state anxiety. Four females were in the top six for pre-scan anxiety in the experimental group (positions 33,32,31 and 29). In the control group males took the top two positions and females the next two down (positions 46 and 47).

8.4 Limitations

Researchers agree that the two barriers to overcome are: level of anxiety/distress and participant's movement. The ethics application stated the following research question was difficult to assess: "Can an immersive virtual reality (VR) simulation be used to predict whether an adult patient will endure a MRI brain scan procedure with no movement?".

No-one terminated early. At Christchurch Hospital, usually one patient a week requires sedation for anxiety, where 60% of the 200 scans per week involve the head (120), so these figures are approximately in keeping with Munn's findings (Munn, Moola, et al., 2015). However, in this experiment all participants who have been included in the data completed their MRI scan with good diagnostic images, indicating participant movement was satisfactory and the medical scan successful. Both barriers were overcome sufficiently. This presents a lack of data in determining when patients will bail out of the scan process. Focus for the main study concentrated therefore on determining the level of anxiety experienced, dropping this original hypothesis from the main study.

As all participants completed the MRI we do not have a figure to consider reaching through prediction. However we can look at the information that the data has given. The experimental group have lower anxiety scores at all points. It is suspected those patients agreeing to take part may have been more relaxed at the outset. Maybe they were of a less anxious nature (anxiety as a personality trait is lower). Maybe their age was a confounding factor (the control group were all over 45 years of age). Maybe they were on medication which made them less anxious (those on medication could not be ruled out of the study as this would have excluded a large proportion of the patients). Or maybe the VR process took away one element of the unknown, that of the procedure they were about to face. It is known that often MRI intervention in any form helps bring down anxiety in the scanner (Munn, Pearson, et al., 2015). Patient profiling using the full STAI questionnaire may give a clearer picture of personality traits and disposition to anxiety, although with the full twenty questions this may prove more distressing and time consuming than the short form used and counterbalance any advantage. (See recommendation R1).

Small sample size limited the study. MRI staff experience one person a week who is unable to complete their MRI scan without further intervention of sedation. This one goes up to twenty who are anxious. On this premise it was hypothesized that if there were a population of twenty per week and the user experiment ran for four weeks the numbers, dependent on patient take-up reaching 75% , a sample size of thirty in each group was feasible. In reality, take-up averaged two patients a week (13% of that hypothesized). The high risk of not having enough patients agreeing to take part was identified early on. Alternatives of other venues and running outside of hours were investigated. Time spent planning upfront to secure authority for additional support proved valuable as this later played out in the form of bespoke weekend shifts. This resolved the issue with new equipment being installed mid-way through.

From the outset, introduction of a new MRI scanner both on site and at a neighbouring hospital gave a fixed time period for the user experiment to run. By this milestone only a total of thirty patients (fifteen participants in each group) had gone through. Of these, three were out-patients. Now, with the introduction of the new scanner, all out-patients would be going to new facilities elsewhere. A sample size of at least thirty each was desired to benefit from central limit theorem. To resolve this problem at substantial on-cost to the hospital two extra weekend shifts (of two days each) were scheduled and an additional fifty out-patients from the waiting list were sent an appointment with an invitation to participate in this study.

Appointment times were every thirty minutes, with patients arriving forty five minutes earlier than their MRI booking in order to facilitate the study. The problem of sample size was compounded with a further self-selection bias introduced on randomness of group allocation. Some in the control group were those where to meet MRI appointment times it was not possible to offer VR. It was felt this still retained an element of randomness but comprised the control sample size with control numbers slow to increase and the resulting sample unbalanced on size (eleven participants) and age (all over forty five years).

There were two key technical challenges encountered. The first was the researcher not being able to see what the user was experiencing. The second, the display resolution possible using a mobile solution was not sharp enough to give a high quality experience. Both challenges could be resolved using an alternative device such as an Oculus Rift which gave visibility for others involved in patient care by displaying what the user could see via a PC screen and was capable of running models developed in a higher resolution environment such as Unreal Engine. This came at the expense of the mobility that the Gear VR headset offered but worthy of trial. However the head mounted display (HMD) alternative available for the study (a DKII Oculus headset) was found too uncomfortable for potentially delicate users who may have recently had brain surgery. A consumer version may be more suitable or delicate users may not be a suitable audience for VR unless an alternative to a standard head mounted display is available. Alternative screen sharing applications were attempted in pilot but proved too complex or impractical to set up and run within the confines of the experiment. VR has difficulty capturing spatial awareness so the proximity of the bore was difficult to replicate in VR. This was a recognised issue (Steed et al., 2016). One patient suggestion was to pack around the patient with cushions to give the sense of enclosure.Another patient pondered the efficacy of VR in preference to video.

Notwithstanding VR technological issues, running the study within the hospital environment has yielded many items worthy of note for future studies with the overall protocol requirement being for flexibility.

8.5 Study Protocol

The study must not slow down day-to-day operations of the MRI unit or any other part of the hospital with the impact on other staff and their work practices kept to a minimum. This was the overriding study constraint.

Study schedules need to be flexible. An urgent case may present at any time and hospital work will flow around this accordingly. Any tasks related to the study needed to do the same. So a schedule was set with a quick revision at the end of each day in preparation of the next. The MRI lead would phone in the morning to inform of the time to come in if circumstances had changed from the night before. On arrival the current situation was assessed and work of the day planned. This remained fluid in response to the events of the day.

The study area needed to be kept as a functional space 24x7 so all equipment was required to be packed down at the end of each day.

This led to daily transportation of equipment and an extra period for set-up and pack-down. Where to park became an important consideration.

Alternatively give careful thought and advance warning for storage needs. Areas available to store equipment may not be accessible at the other end of the day to set up or put down as the working day may extend from early morning until late into the evening (MRI scanner available 7am to 10pm). Common areas are often accessible only during the normal work day hours (e.g. before 5pm).

Shared hospital equipment may need to be made available on demand (e.g. blood pressure monitor) or alternatives sought. Similarly sourcing of simple equipment (e.g. over bed table) may take a while so request in good time.

Be aware of infection control. Attend relevant briefings. In a couple of instances it was decided not to involve participants who were infectious (e.g. hospital procedure dictated no paper notes could be used making it difficult to administer questionnaires in a uniform and safe manner for all).

Ensure management approval was sought and granted where additional tasks are being considered before the request is made to members of staff. (e.g. volunteer participation of staff members in the pilot trial).

Consideration of patient movement (via beds or wheelchairs) needed to fit together easily and conveniently to ensure no additional workload was being created for porters.

Services of medical staff and engineers are an act of goodwill over and above their daily work. In all interaction allow plenty of time.

Be aware of unavoidable breaks in running of the study due to maintenance work (e.g. rerunning cables overhead in suspended ceiling cordoned off study area for the day or a fault occurred with the scanner needing repair). Some could be planned for but others not.

Working in the MRI environment also presented the technical issue of slow degradation of equipment in the scanner room. The IOM sensors near the scanner degraded until they no longer functioned. When backup sensors were ordered from the manufacturer it was found the original stock model was no longer produced and an alternative blue IOM device supplied instead. A second pair of the same were sourced as a back-up to these.

8.6 False positive threshold

To be of statistical value, false positives not > 5% have been assumed (p<.05). i.e. where VR scan simulation shows patient can cope but when in the real MRI scanner they cannot. For a longer term goal, this might not be practical as in the medical environment this is brought down to 1% or .1% . It is not sufficient to just take before and after measurements, during is also needed. Some people when they are sick, struggle to regulate their temperature and so absorb the electromagnetic wave (radio) frequencies (RF) around them with heat. Using only before and after measurements would make it hard to work out their false positives, so if they could be monitored the whole time, at least it could be detected when the RF's were introduced and when they are starting to get sweaty and enable differentiation between nerves and being heated up by the scanner.

However, use of the simple IOM sensors in the MRI scanner was not possible due to the potential for peripheral nerve stimulation (PNS). Three types of sensors were investigated with the conclusion the bespoke IOM plug could not be replaced with a fibre optic cable by medical engineers. To monitor during scanning, a more sophisticated MRI bio-monitoring system would be required (R3). This is detailed in Appendix F.

8.7 Summary

My contribution is the experience and documentation of running an experiment of a novel MRI intervention, a VR brain scan simulation in a hospital setting. The logistics, planning and impact of introducing this within the day-to-day running of the MRI hospital environment should not be underestimated. A protocol for doing so has been developed and documented.

Since it was known that exposure did not statistically matter the experiment was folded, merging the between groups together and enabling the study of 'stage' across all forty three participants. A strong positive correlation has shown that given a patient's state anxiety score before any intervention (pre-scan), their score during the MRI can be predicted. VR may still hold a therapeutic effect.

For the hospital the real problem is when patients bail out or start to move in the MRI scanner. The questionnaire has a high correlation. If the hospital integrates the use of this questionnaire into their current MRI process, there is a good chance they could filter out the people who terminate early. To date I have been unsuccessful accessing CDHB figures for early termination to work with. However this information could be gathered from the outset. Firstly I recommend giving all patients the questionnaire to see how scared they are. This would give medical staff an indication that some intervention may be required.

8.7.1 Recommendations

There are two main recommendations to the hospital from this thesis:

R1 - Use STAI Y-6 Questionnaire before MRI scan.

R2 - Start recording data for future use.

These address the primary concern of MRI staff at Christchurch Hospital for prior detection of patients who may have an unsuccessful MRI scan. The other recommendations consider at how the VR study

could be improved for future therapeutic use (to be added).

R1: USE STAI Y-6 QUESTIONNAIRE BEFORE MRI SCAN

At the first step, the desired audience, did not engage with the experiment, presenting the concern of a strong self-selection bias in the data. The desired audience are those mostly likely to terminate their MRI scan early due to anxiety and likely to be patients of a more cautious nature. Selection bias brings in the practical problem that those patients who probably would have bailed out were never able to be tested because they needed to consent beforehand. So a change to the experimental procedure is required that allows participants that are scared to the degree they refuse to take part to answer the STAI Y-6 short form questionnaire.

To avoid self-selection bias the next study should try to run this questionnaire prior to having to fill out a consent form. Present the STAI Y-6 (short form) questionnaire at the outset of the hospital MRI receiving process and ask the patient to complete the questions. Seek approval from the Human Ethics Committee (UC HEC) for post-hoc consent.

R2: START RECORDING DATA FOR FUTURE USE

Data needs to be gathered related to the problem. There are two cases which are fine: patients who are not scared and don't need sedation or they are scared and do need sedation. The problem is those patients who claim they are not scared, but then they are, or who request sedation but really didn't need it. These may be thought of as false positives and negatives respectively. The questionnaire gives some indication on this and a potential tool for the MRI team to use. In addition, the MRI lead at Christchurch Hospital has noticed a recent increase in the requests for sedation at the outset from a patient's general practitioner (GP). This was within the period of study and although it could not be officially referenced at the time, would be very useful to collect going forward. Given the large correlation found the recommendation is to investigate further. Local observation gives strength to this.

It is important to keep track of bail outs, a known financial problem. Doctors' experience estimates 10% of MRI patients are anxious with 1 in 100 being claustrophobic. Research shows this number to be up to 20%. Our attempts to get to the data were not successful despite contacting several people so the recommendation is if the hospital would keep track of the STAI questionnaire and if they would keep track of the premature terminations then this information could be used to run the statistics. Doing so would define predictive power and then the model could be used as a tool to predict whether patients are likely to terminate early.

A scan can have three outcomes: successful diagnostic images, unsuccessful images or scan terminated early. In order to achieve the result patients may require a level of intervention. That intervention may range from reassurance through to full sedation (GA) given. The data in this study with pre-scan state anxiety only relates to successful diagnostic images so further work is required to gather data leading to unsuccessful images or early termination of scan. Data recorded should include; type of MRI scan (e.g. 'head', 'cervical' or 'spine') and success/ useful diagnostic images) equal to 'y' or 'n' and the binaries given in Chapter 3 section 3.5 (Experimental Data Input). If a scan has been unsuccessful some follow-up action is likely to be required so to enable more comprehensive analysis this needs recording, action equal to reschedule 'r' or cancel 'c' scan, plus intervention required and cost (financial to DHB and temporal to patient). The one case in the study (who did not participate) was re-scheduled with a stronger level of sedation.

The statistical tool would be to run a discriminant analysis (or DFA; discriminant function analysis) to see how we can best separate a set of groups. This is akin to a reverse ANOVA. To do so we need to set the prior probabilities. Data gathering of terminations will aid in this. Current knowledge can assume that the 'chance' of a patient being in the anxious group is worst case scenario ten out of one hundred so 10%. It would be preferable to have equal sample sizes of gender and variety of age. It may also be helpful to consider the trait anxiety to see if this assists with assessing anxiousness in patients as well as state anxiety. However there is not a short form questionnaire relating the trait anxiety and a long form may prove too stressful for those delicate cognitive patients. (Tluczek, Henriques, & Brown, 2009).

A third recommendation is to address the difficulty recording patient anxiety during the MRI scan itself.

R3: RESOLVE MEASURING ANXIETY IN THE SCANNER

With the above recommendations in place, if or when a patient does bail from their scan, for quality research it is critical to have the data to interpret. Building on van Mindes's work pinpointing anxiety in the scanner, it is recommended that the hospital invest in an MRI friendly platform to enable gathering of anxiety data as simply as possible. The second option detailed in Appendix C, Pricing Quotes Summary table allows up to sixteen channels of physiological data to be supported. This is of particular benefit in a facility with more than one scanner which can be scaled up to optimise use of the data harvesting platform. The key component being delivered is fibre optic cabling and MRI friendly sensors. The threshold points at which the patient terminates their scan would then be available to analyse already within a digital environment.

8.7.2 Recommendation for future work in VR

It is recommended to repeat on a higher resolution platform where the real environment is mimicked. Retain the physical environment of trolley bed with Smith mattress. Initiate pre-recording of patient response through the MRI so comparisons can be made with data in situ. Allocate at random to three groups, equal in size, gender and age group. Number these 1. treat as normal procedure (music), 2. offer video of MRI scan procedure, 3. treat with VR. As new scanners are introduced the problems lessen. For a set period, pre-record data of those patients requiring intervention and details of intervention used. Offer full STAI questionnaire at the beginning to establish user anxiety profile. The MRI questionnaire may also prove a useful alternative worthy of investigation prior to selection of profiling questionnaire.

Chapter 9

Conclusion and Future Work

What can we conclude? If virtual reality does not create a difference between groups, VR may still hold a therapeutic effect. For prediction this leads to a position to consider which of the two was the better predictor and hence answer the original question posed by the Hospital, "Is VR useful in predicting anxiety of patients during MRI?"

9.1 Conclusion

No statistical significance was found between groups but some commented they appreciated the experience. My findings were that VR is not scary for those who took part, individually anxiety levels came down (although not proven statistically significant). It offers the opportunity to experience some of the unknown the procedure may hold. It may be a step forward in making the MRI experience a little less daunting, that seems to work for some people. However, many do not want to be offered VR. Why? This again needs investigation. Maybe it will prolong their time at the hospital, or they prefer to get the procedure over and done with.

There were limitations on the control group; their age was greater than forty five years, some have had an MRI before and the sample size of eleven was small and out of balance with the experimental group. Further work is required to hone in on their user profiles to assess how useful this intervention may be.

So, "Did VR not work out? - very often technology is not the solution. Usually pen and paper, a couple of questions is much more powerful and it is extremely practical and cheap. You don't need equipment, you don't need electricity, it is so much easier. Maybe for therapy it would work but that is another study. Here a simple outcome is what has been found.

Comments from patients were both positive and negative. We need to be wary of the novelty effect but that said for some, their comments alluded to VR helping them tackle their MRI, so for those patients it may have been successful. The area of VRET is certainly expanding but currently it lacks large scale clinical trials. A second front is to recommend future study in the area of therapy.

This thesis stepped through the research questions to understand if a significant difference between VR and non-VR groups (in the sample) can be ascertained. In order to tackle the question from hospital staff "Is VR useful in predicting anxiety of patients during MRI?" there should be consistency between the VR group and the non-VR group, so that the process of measuring does not change when VR is applied. i.e. There is no 'observer effect' (de Bianchi, 2013). If no significant difference is found, it is acceptable to consider a logical regression analysis on the experimental group to investigate the relationship between

anxiety during VR and anxiety during MRI. This was the case in our study. It was found that yes, VR could be useful in predicting anxiety during MRI but consideration was also required to how much the variability was due to VR and how much to other factors. This led to folding of the experiment to consider how much variability was due to stage within the MRI experience and that was found again to be significant with the pre-scan anxiety also useful in predicting anxiety during MRI, with not such a strong relationship but more simply and with a lesser outlay.

The guidance below was written to help others in the future do it differently.

9.2 Future Work

A future option may be to just ask the patient if they would be interested in taking part in a virtual scan experience before their scheduled procedure without actually making an offer for them to take part. This may give a clearer indication of how receptive the population may be, without inducing further anxiety. It may also prove helpful to know if these patients shared a similar trait anxiety profile by asking them to complete trait questions, as this study only used six state anxiety questions from the STAI.

There are some other basic needs in the hospital at the moment. Play therapy is being used for children receiving bone marrow transplants and chemotherapy (sitting with lines in), but play therapy resource is scarce. You cannot experience the nausea that follows but patients could come into the lounge and see all the environment. This simulation extends to use in other areas in radiography. The final section considers exploratory work carried out while completing this thesis and potential leads for further study.

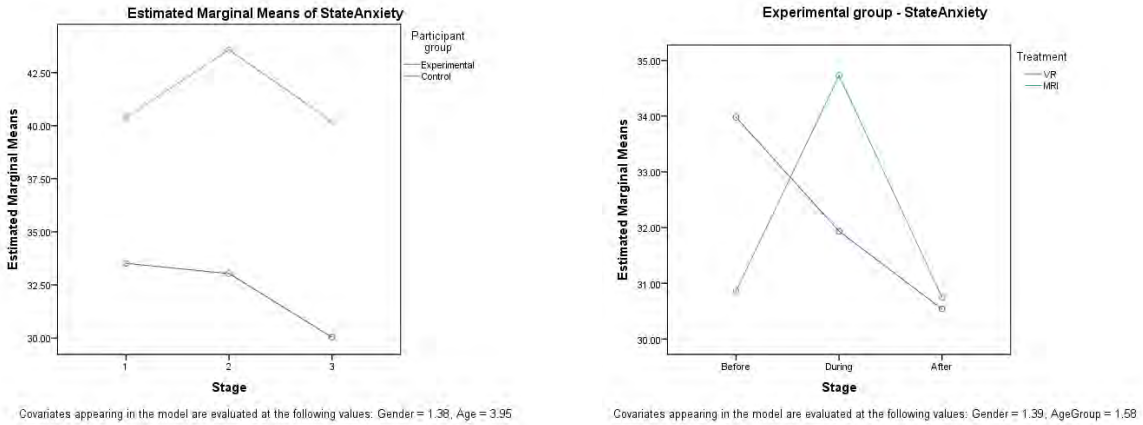
9.3 Exploratory Statistical Analysis

Neurological research is moving toward a culture of openness and data-sharing (Gilmore, Diaz, Wyble, & Yarkoni, 2017). In this context I offer the data files for further research by desk review, available by request. There is a wealth of information still to be harvested from the current data file. Some data avenues (below) have been identified while completing this thesis and may be suitable for future work by desk review.

1. Correlation analysis taking account of the individual subjects' baseline anxiety measures pre-experiment using Pearson partial correlation.
2. Pretest-Posttest experimental design using two-way mixed ANOVA to look into main and interaction effects within-subject and between-subject.
3. General linear model one-way repeated measures ANOVA run on Experimental group to determine group differences.
4. Regression analysis comparing pre-test anxiety measures with post test.
5. Regression analysis considering repeated measures ANCOVA in R using covariates of age-group('younger'/'older') and gender.
6. Joint consideration of blood pressure and heart rate readings may give more significance to data findings. They both were recorded on the same piece of equipment and should be interpreted with knowledge of best research practice for these medical markers.

9.3.1 Findings of Exploratory Work

1. Significance was found initially, but after consideration of pre-experiment anxiety measures, for both STAI and HR this was no longer significant.
2. Significance found for STAI and HR.
3. No significance found between those who had VR and those who did not.



(a) Between-subject (b) Within-subject

Figure 9.1: One-way repeated measures ANOVA estimated mean values at stage before, during and after

4. No significance was found for all anxiety measures (STAI, HR, BPS, BPD, SCL. Only for confounding variables of BP and Age.
5. Significance was found for all anxiety measures (STAI, HR, BPS, BPD, SCL. Trajectory of anxiety was predicted for younger females which showed a gentle downward curve for VR and a spike for MRI.

Chapter 10

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Appendix A

Existing Hospital Protocol

A.1 Magnetic Resonance Imaging

a) Referring doctor sends through a request for a MRI.

b) Once received, this request for MRI referral form is shown to a Radiologist to protocol and triage the form. This defines the scan process to be performed and support required.

c) The patient is then given a booking appointment (including time and location).

d) Before the appointment the Radiology assistant rings the wards to check how the patient is travelling and asks if the patient has any other special requirements. This includes to see if the patient is able to consent themselves or if they require sedation.

e) When the patient arrives they are asked to complete the MRI safety questioner and contrast consent form if they are to receive contrast

f) At this time the patient is given a brief explanation to what the examination involves. If the patient asks questions they will be answered.

g) The safety questioner is reviewed by the MRI staff and the patient is asked to remove all metal that is a concern. The reviewer checks if any questions have been missed. Is any metal not compatible with the scanner? Is there anything which needs to be researched before the scan can take place? Do the scanner settings need to be changed?

h) The patient enters the room and is asked to lie down on the MRI bed and the head is rested in the bottom of the head coil.

i) The patient is given the safety buzzer and told to squeeze it if they need to come out.

j) The patient is given ear plugs and head phones, they also get to request the type of music to be played.

k) A bolster is placed under the patients legs for comfort, if it is cold they may also be offered a blanket.

l) Once comfortable the upper part of the coil is slid over the patients head and a mirror is adjusted so they can see out towards their feet.

m) The staff member confirms with the patient they are OK before they leave the room to start the scan. No response from the patient or excessive movement would trigger the MRI technician to stop the scan and take action.

A.1.1 Impact on Existing MRI Protocol

MRI technical lead will consult with Neurology Department before study commences to confirm what will be happening and how best the two departments can work together. It is unlikely that the consultant neurologist will discuss directly with their patient before the MRI appointment is scheduled. Following c) for patients able to consent the Lead MRI technician will explain the purpose of this study and ask if the patient is willing to participate. For those who give consent, ensure participation in the VR simulation is recorded on in-patient medical notes. For out-patients record on their hospital medical notes and ensure they will be accompanied home from the MRI scan by a responsible adult. Aim to have a full night of normal sleep preceding participation in the experiment, as tiredness increases susceptibility to adverse VR symptoms. Participants will be asked to complete a questionnaire regarding suitability for the VR simulation. See Appendix B - Participant Suitability for VR Simulation Questionnaire. Patient bookings will need to be increased by an additional 30 minutes for those who have consented to take part in this research and pass the suitability for VR questionnaire. Presence of MRI Technical Lead staff will need to be available for this additional time and hence the cost to the hospital will equate to an additional 30 minutes of staff and MRI scanner time per participant appointment.

Appendix B

Human Ethics Approval

This appendix contains authorities and participant information and consent forms ordered as below:

- Consent from Human Ethics Committee
- Approval from Maori Director of Research
- Approval from MRI Department, Canterbury District Health Board
- Revised Human Ethics Committee (UC) Application
- Information Sheet for Study Participants (including MRI Dialog to be included courtesy of Mr Peter Dooley -CDHB MRI Charge Technologist).
- Consent Form for Study Participants
- Consent Form for Virtual Reality Study Participants

HUMAN ETHICS COMMITTEE

Secretary, Rebecca Robinson
Telephone: +64 03 364 2987, Extn 45588
Email: human-ethics@canterbury.ac.nz

Ref: HEC 2016/32

31 May 2016

Helen Figg
HITLab
UNIVERSITY OF CANTERBURY

Dear Helen

The Human Ethics Committee advises that your research proposal "Detection of Patient Anxiety Threshold Using a Pre-MRI Virtual Reality Brain Scan Simulation" has been considered and approved.

Please note that this approval is subject to the incorporation of the amendments you have provided in your email of 25th May 2016, and the following:

Please ensure a letter from Dr. Mike Hurrell and Dr. Anthony Butler is forwarded to the HEC prior to the commencement of data collection.

Best wishes for your project.

Yours sincerely.

pp. R. Robinson

Jane Maidment
Chair
University of Canterbury Human Ethics Committee

Ngāi Tahu Consultation and Engagement Group

UNIVERSITY OF CANTERBURY
Te Whare Wānanga o Waitaha
CHRISTCHURCH NEW ZEALAND

30/05/2016

Tēnā koe, Helen

Re: Maori Consultation

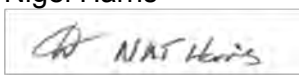
This letter is written on behalf of the Ngāi Tahu Consultation and Engagement Group. Your proposal has been considered and acknowledged as an extremely worthwhile and interesting project.

It is well considered and the researcher is clear about how they ought to take any participants' and Māori (cultural) needs into account.

Thank you for engaging with the Māori consultation process. This will strengthen your research proposal, support the University's Strategy for Māori Development, and increase the likelihood of success with external engagement. It will also increase the likelihood that the outcomes of your research will be of benefit to Māori communities. We wish you all the best with your current project and look forward to hearing about future research plans.

The Ngāi Tahu Consultation and Engagement Group would appreciate a summary of your findings on completion of the project. Please feel free to contact me if you have any questions.

Nga mihi
Nigel Harris



Acting Māori Research Consultant
Senior Projects Manager
Office of AVC Māori
Te Whare Wānanga o Waitaha
Private Bag 4800
Otautahi Christchurch 8140
Aotearoa New Zealand
Phone +64 3 364 2987 ext 6120
cellphone 0273950134
nigel.harris@canterbury.ac.nz

Canterbury
District Health Board
Te Poari Hauora ō Waitaha
Radiology Services

Mr Peter Dooley
MRI Unit
Christchurch Hospital
Private Bag 4710
Christchurch

Dear Peter

Regarding your project:

> **Detection of Patient Anxiety Threshold using a pre-MRI Virtual Reality Brain Scan Simulation.**

I give you permission to conduct this research in the CDHB Radiology Department.

Yours sincerely

Michael A Hurrell

Michael A Hurrell
Director MRI Unit
CDHB

Prof Anthony Butler, Radiology.
University of Otago.

Department: **College of Engineering / Human interface Technology Laboratory**
Telephone: +**64 3 364 2349**
Email: **helen.figg@pg.canterbury.ac.nz**
Date**: 11th April 2016**

Detection of Patient Anxiety Threshold using a pre-MRI Virtual Reality Brain Scan Simulation
Information Sheet for Study Participants

My name is Helen Figg. I am a research student studying at the University of Canterbury for a Master's degree in Human Interface Technology. I am the principle researcher looking at how modern technology can help improve the experience of patients in the MRI room. It is not known how you may react during your MRI scan without going through the experience itself. We want to be able to ensure the procedure runs as smoothly as possible for you. This research is trying to predict whether experiencing a simulation of the MRI scan in a computerised virtual environment will help predict how a patient will respond in the scanner itself. If successful, we may have a tool our MRI technologists can use to help minimise the use of sedation.

If you choose to take part in this, your involvement in this project will be to participate in one of two groups, allocated alternately to those taking part. At points before and after the experiment you will be asked to complete a questionnaire asking you to reflect your current state of anxiety on a scale of 1-4. There will also be some follow-up questions one month later. You will also be asked to wear sensors on your fingers so that your heart rate and skin conductance (how much you perspire) can be measured. One group will undertake an MRI scan as normal, without intervention. The other group will be asked in addition to undertake a simulation of the MRI scan in virtual reality (using head mounted display goggles) lying down. In both experiments you will be wearing a frame around your head to ensure minimal movement plus earplugs and headphones. As a follow-up to this investigation, you will be

asked to answer a few simple questions regarding how you feel about the experiences.

Please note, if you are currently suffering from a viral infection, e.g. cold, flu, or a contagious condition you may be asked to wear a lightweight mask or cap to safeguard everyone's health.

If you have not had an MRI before you may like to know MRI stands for magnetic resonance imaging. It uses a strong magnetic field & radio waves to create images of your head & body. It does not use ionizing radiation. When you arrive at the radiology department one of the MRI technicians will come and see you and will go through your safety questionnaires and answer any questions you may have. Our primary concern is for your safety with regard to the MRI scanner. Therefore, please answer all the technicians' questions fully about your history, even if it is from a long time ago. You'll be asked to remove all metal accessories such as watches, earrings, hairpins & piercings. If your scan requires you to have intravenous contrast a small needle maybe inserted at this point. The MRI machine is shaped like a large doughnut. The scanner is open at both ends and doesn't hurt or spin around you. The area we're imaging needs to be in the centre of the magnet meaning you will go in head first and you head will be in the middle of the scanner. You'll be taken into the scan room and asked to lie down on the scan table. We'll make you as comfortable as possible. You'll also be given an emergency buzzer for your peace of mind so that you can always contact us to stop the scan should you need to. During the scan the machine makes loud electronic noises as loud at a lawn mower. For this reason you'll be given headphones or earplugs to wear. We have an intercom so we're able to talk to you between the scans and you can talk to us. In order for the machine to acquire its images, equipment called coils are placed near the body part that's being scanned. This will mean you'll have a piece of equipment placed over your head, which also allows you to see out through the use of a mirror. Your report will be sent to the doctor who requested the scan and you images will instantly be available for them on their computer.

In the performance of the tasks and application of the procedures there are risks of feeling disoriented if using the VR headset. Your neurologist has been consulted to ensure your participation is in line with their advice. Details of VR risks will be on the consent form.

Participation is voluntary and you have the right to withdraw at any stage without penalty. You may ask for your raw data to be returned to you or destroyed at any point. If you withdraw, I will remove information relating to you. However, once analysis of raw data starts on 1st June 2016 it will become increasingly difficult to remove the influence of your data on the results.

The results of the project may be published, but you may be assured of the complete confidentiality of data gathered in this investigation: your identity will not be made public without your prior consent.

To ensure anonymity and confidentiality your results will be identified by a sequentially allocated scan number. This will be the only way of cross-referencing to your identity. Consent forms will be kept confidential in secure physical and electronic storage accessible to the research team.
All data will be kept confidential.

Steps taken to ensure anonymity and confidentiality, if applicable. *Explain who will have access to the data, how the data will be securely stored, who will have access, and that it will be destroyed after a stated period If data is to be stored indefinitely, include an appropriate statement*]. A thesis is a public document and will be available through the UC Library. Please indicate to the researcher on the consent form if you would like to receive a copy of the summary of results of the project.

The project is being carried out as a requirement for degree by Helen Figg under the supervision of Dr Christoph Bartneck, who can be contacted at christoph.bartneck@pg.canterbury.ac.nz]. She will be pleased to discuss any concerns you may have about participation in the project. This project has been reviewed and approved by the University of Canterbury Human Ethics Committee, and
Participants should address any complaints to The Chair, Human Ethics Committee, University of
Canterbury, Private Bag 4800, Christchurch (human-ethics@canterbury.ac.nz).

If you agree to participate in the study, you are asked to complete the consent form and return to the principal researcher or the medical MRI charge technician during your session. A photocopy can be made for you to take with you if you wish.

Helen Figg

Consent Form 1

Human Interface Technology (HITLabNZ)
Telephone: +64 3 364 2349
Email: helen.figg@pg.canterbury.ac.nz

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Te Whare Wānanga o Waitaha
CHRISTCHURCH NEW ZEALAND

Detection of Patient Anxiety Threshold using a pre-MRI Virtual Reality Brain Scan Simulation

Consent Form for Study Participants

I agree for the research study to record my age, sex, postcode and ethnic group and participation.

I have been given a full explanation of this project and have had the opportunity to ask questions.

I understand what is required of me if I agree to take part in the research.

I understand that participation is voluntary and I may withdraw at any time without penalty.
Withdrawal of participation will also include the withdrawal of any information I have provided should this remain practically achievable.

I understand that any information or opinions I provide will be kept confidential to the researcher and research MRI team lead and that any published or reported results will not identify the participants. I understand that a thesis is a public document and will be available through UC Library.

I understand that all data collected for the study will be kept in locked and secure facilities and/or in password protected electronic form and will be destroyed after five years unless there is a medical legal reason to store for longer.

I understand the risks associated with taking part and how they will be managed.

I understand that I am able to receive a report on the findings of the study by contacting the researcher at the conclusion of the project.

I understand that I can contact the researcher Helen Figg (helen.figg@pg.canterbury.ac.nz) or supervisor Christoph Bartneck (Christoph.nartneck@canterbury.ac.nz)for further information. If I have any complaints, I can contact the Chair of the University of Canterbury Human Ethics Committee, Private Bag 4800, Christchurch (human-ethics@canterbury.ac.nz)

I would like a summary of the results of the project. (A summary of results will also be available via the HITLabNZ website)

□ By signing below, I agree to participate in this research project.
(Please mark with a tick √ **)**

Name:

Signed: _____ Date: _____

Email address *(for report of findings if you require)*:

Please return this form to Helen Figg or your charge MRI Technician before leaving the MRI facility.

Consent Form 2 (VR)

Human Interface Technology (HITLabNZ)
Telephone: +64 3 364 2349
Email: helen.figg@pg.canterbury.ac.nz

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Detection of Patient Anxiety Threshold using a pre-MRI Virtual Reality Brain Scan Simulation

Consent Form for Virtual Reality Study Participants

(Please mark with a tick √)

Do you have any pre-existing binocular vision abnormalities □ Yes □ No

Do you have a psychiatric disorder? □ Yes □ No

Do you suffer from, or have a history of seizures (i.e. have severe dizziness, epileptic seizures or blackouts) □ Yes □ No

Do you have a contagious condition, infection or disease (particularly of the eyes, skin or scalp)? □ Yes □ No

Name: _____

Signed: _____ ___ Date: _____

Email address *(for report of findings if you require)*:

Please return this form to Helen Figg or your charge MRI Technician before leaving the MRI facility.

Appendix C

Development Detail

C.1 Prototype Development

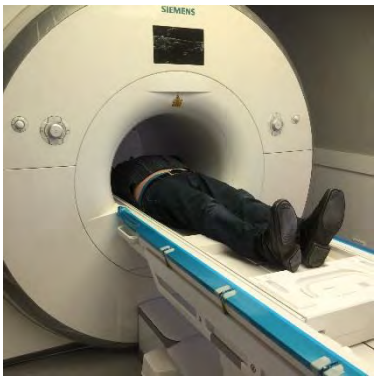
Due to time constraints, following an initial brief from the researcher and MRI team lead, a prototype was iteratively developed in the lab and installed onto a Samsung 6 Edge mobile phone with audio voiceover from a medic taking the user through a simulation MRI scan. On handover, further visual refinement was required and outside services brought in to assist. The researcher wrote a brief of what was required (detailed in the next section.

C.1.1 3D Modeling Brief

3D Modelling MRI Project Brief

The Problem

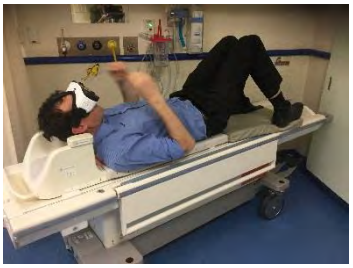
The Researcher's task is to create a virtual reality experience as close to real life as possible to simulate an MRI brain scan.



An application has been developed but it requires an artistic 3D modelled environment to bring that element of realism and ensure the research project is worthwhile. A 3D model of the MRI scanner has already been sourced from the manufacturer and currently used.

The Opportunity

To put out to tender for a cost-efficient design of the virtual MRI scanner room beautifully made with full rendering, lighting and texture. The requirement is for a simple medical space but it needs to look right, creating a realistic experience and feeling of presence when the patient looks around the room.



Current VR Application.

Take away the computerised 1980's software feel replacing with a simple environment and realistic lighting. If present, the figure would be better relaxed, a darker grey colour with a high level of transparency.

Terms of Engagement

Sign NDA.
Create a 3D Model compatible with Unity (5.3.4) which can be used by the existing application.
Export models to Unity FBX or other supported format. Rendering needs to be done in Unity.

Potential Tender

Brief: Very minimal, medical room with door and control room window and ceiling image. Needs to be fully rendered and beautifully made, by a 3D artist. (In the existing application, the camera will be positioned for user to sit on the bed, look around, face the control room, lay down, travel back into the bore, stay still for the scan procedure to complete and be brought forward out to the original position. Behind the tinted control room window is an MRI medical technician standing behind a monitor screen.)

Please quote estimated work hours, duration and estimated deliverable date. Screen shots and priorities overleaf. Further material to follow.

Contact:

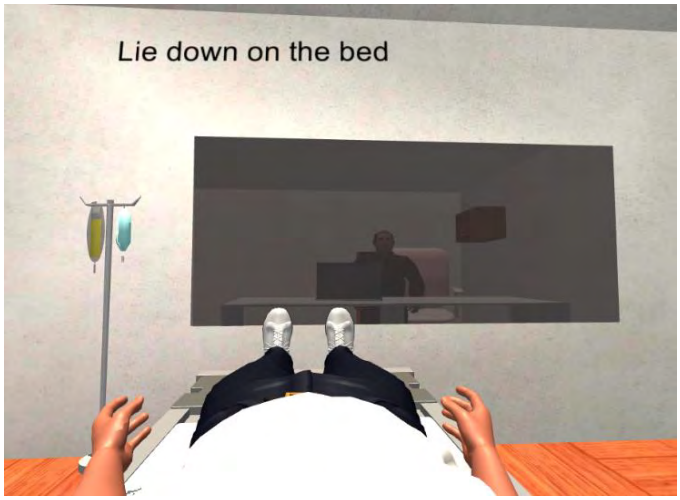
Helen Figg, The Human Interface technology laboratory (HITLabNZ), Christchurch, 8041, New Zealand

Helen.figg@pg.canterbury.ac.nz or hfi16@uclive.ac.nz

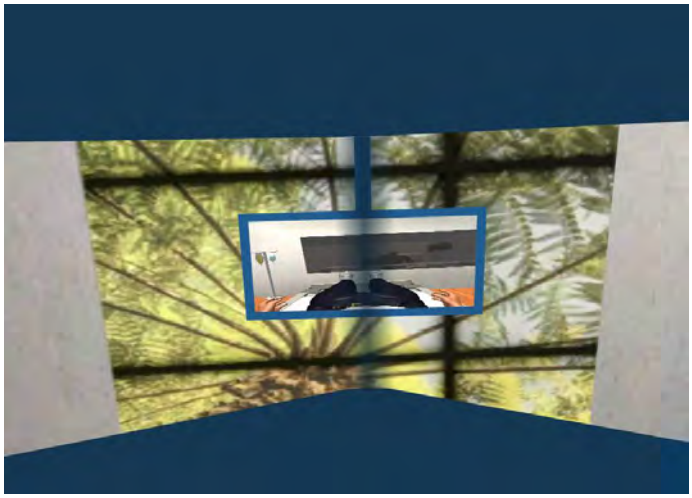
Screen shots from Current VR application

Approach to sit on the bed

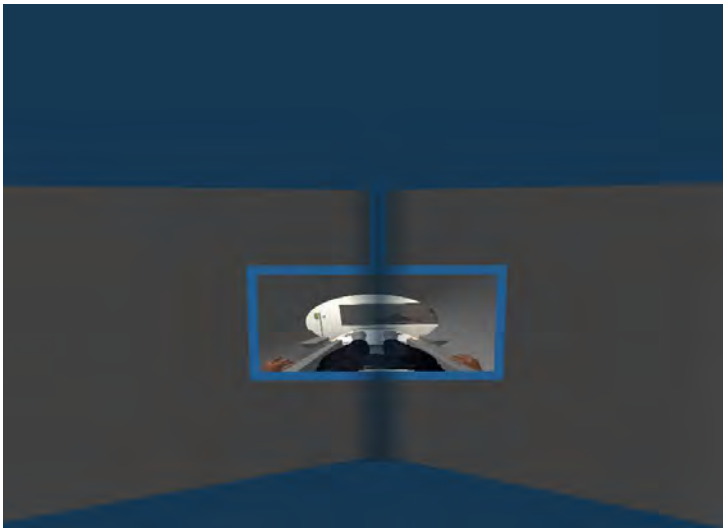
(A door is visible on the patient's left)



Look around until you can see the control room



Going into the bore of the scanner



The view from inside.

The application will reverse back out after the procedure has completed.

Modelling Priorities

Please tackle in the following order.

1. A 3D model of the head coil if it is unable to be sourced.

Figure 1. Head coil similar to one used in the study
(Photo: https://www.healthcare.siemens.com/ *accessed 2/25/14*)

2. Bring consistency across the user experience in terms of level of modelled detail.
    a) Create a simple, medical room with door and tinted control room window. Include light floor, walls and ceiling.
    b) Remove the figure lying on the bed.
    c) Reduce level of detail in existing models as necessary.

3. Lighting ideally in real time is critical to add a sense of realism. Consider which type of lights are required, where to place them and what characteristics they have.

4. Behind the control room window
    a) add an MRI technician naturally standing behind a monitor screen.

5. If necessary, texture the inside of the MRI model to add to the sense of realism in travelling back into the bore

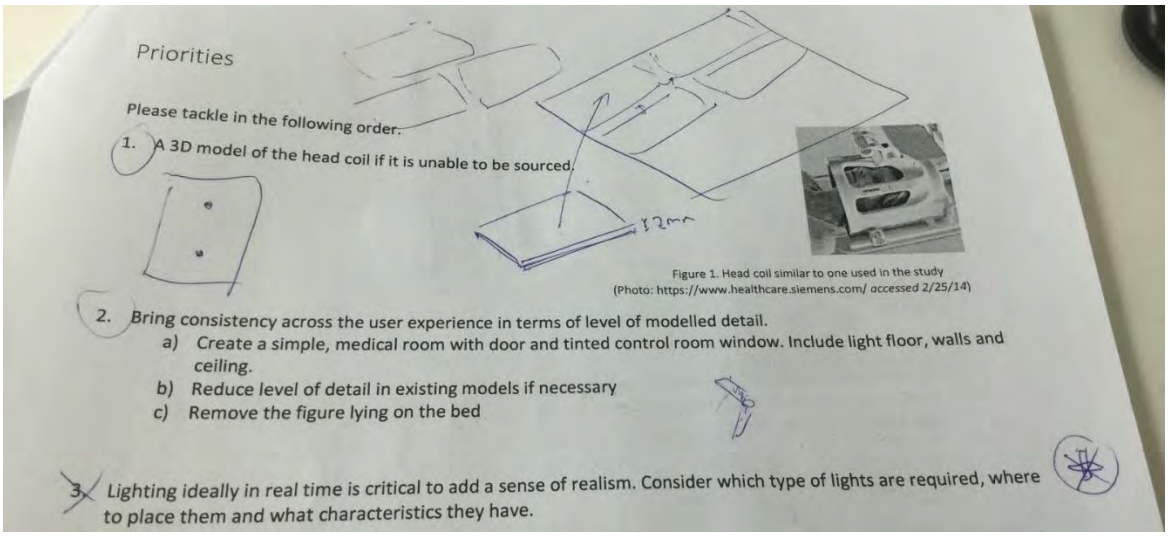
6. To the room add an
    a) illuminated panel in the ceiling as in Burwood (blossom)
    b) outside window

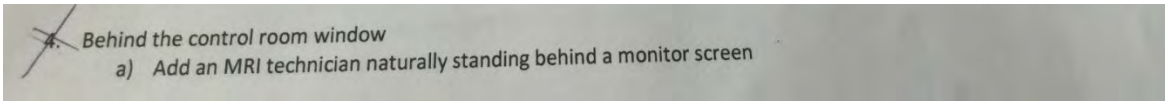
7. Replace the figure removed earlier with a relaxed, transparent and darkened model to further the illusion of presence.

Additional Design Detail Update

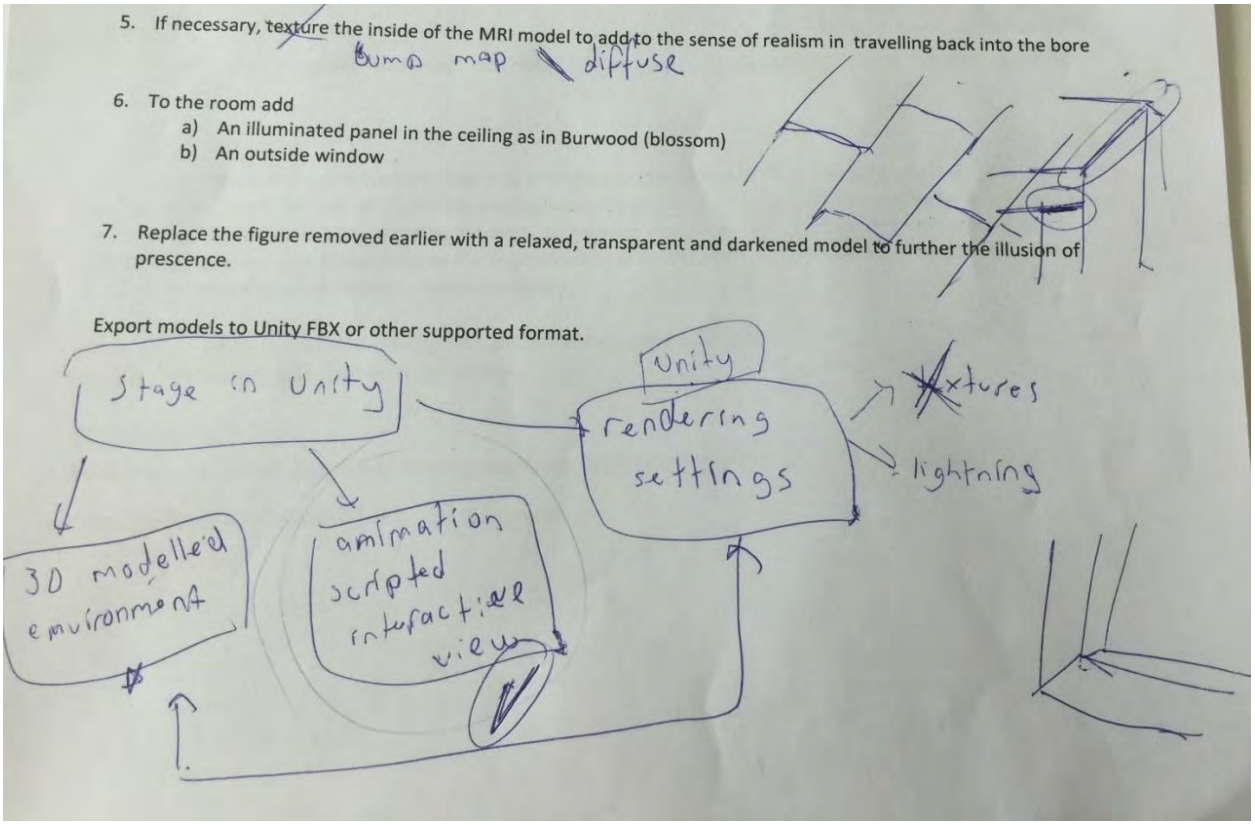
Following a collaborative review session in the Lab 4th April 2016, a revised design brief was issued.

Priorities 1 and 2 remain as is.



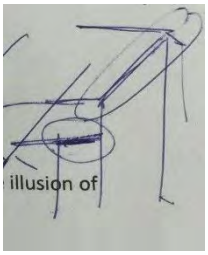


Regarding the lighting, this is better explained a little differently.



There are 3 different components in the Unity environment, 3D modelled objects, the scripts that enable the interactivity of looking around and thirdly the rendering settings.

For the VR application, the second component has been developed and is ready. The other two components are directly connected. Render settings have two components, texture and light. With textures if they are not correct, it is better not to use them, especially in terms of consistency. For the realism, what is important is consistency in the experience.



For the medical room, it is clear and white. Looking at the control room window photo, there is a significant amount of detail. Add details, including screws, to portray the window corner in 3D with a very significant amount of detail (as in the left image). The corner for example, if it has this 1 mm gap, adds realism. Imperfection is the fan of realism. Add the imperfections in the room, like two metal frames not properly touching each other. If it has a gap, it has realism. Place the screws; they do not need to be modelled. Just have a sphere and dig into the depth to look like an object, A direct sphere or a cylinder works, it does not need to have the detail of the screw head. Surfaces can easily be differentiated by grouping the surfaces together, so that all the metal frames are in one group, the panel is another and the wall is another. So one pack of objects may be imported into Unity, knowing all of item are reflective metals. So in render settings they can be given a grey colour and assigned reflection. So, don't put any texture in the model, just set the material properties in the colour, so that all the metals in the room look the same, all the walls look the same and all the other panels look the same within their own group, but they look completely different from other groups. No textures, nothing.

The same for the floor. Creation of this is quite simple. Create a plane on the ground and then 3D model a floor tile as a rectangular prism that has a very little height (like 2mm), then they are placed one after another 2mm apart on all sides. Even better lay in a brick pattern, it will look very realistic and the light effects will reinforce those little gaps and little heights, in a very realistic way.

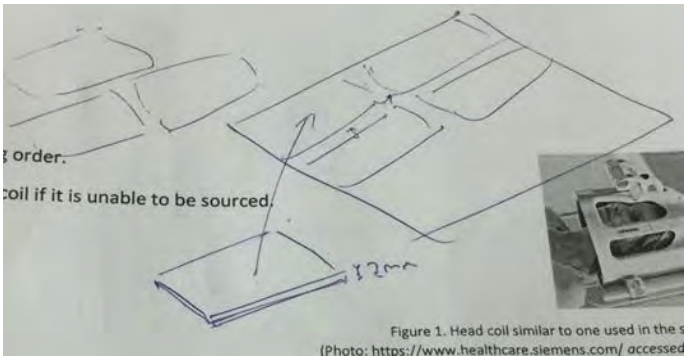


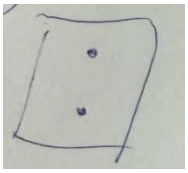
Figure 1. Head coil similar to one used in the s
(Photo: https://www.healthcare.siemens.com/ accessed

We now have a 3D room that has properties which look quite different.

3. Lighting.

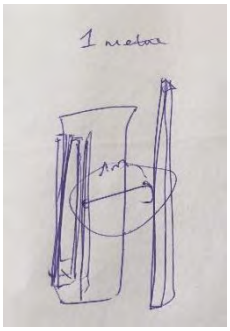
Lighting is a very hard topic to learn so what is suggested is this. Either purchase or get one of the free lightmapping utilities from Utility store assets. There are purchasable and free features and not just objects. This is a lightmap. Go to URL https://www.assetstore.unity3d.com/en/#!/content/6071 which displays a free asset; Lightmapping Extended. What it does is this is an empty room with nothing inside, but the moment the light is put on it looks something like this. There is no detail, no textures, nothing. You are inside the cube and there are two other prisms and probably a sphere. The moment they put the light on it changes significantly. It is like a plug-in and easy to use.

Location of the lights are **already** set. There are two lights on the ceiling. They need to be significantly away from each other. Show ceiling from top view as it is in the physical room. There needs to be more than one light so that more than one shadow is cast. With more than one light it gives that effect in stadiums, if people have more than one shadow and their shadow lessens as it goes away from them because the other light weakens that shadow, it lights over that shadow. This is extreme realism. The key for good light rendering is to have two separate lights that bring the light from different angles. Two is sufficient. There can be four but that adds a burden of extra processing.

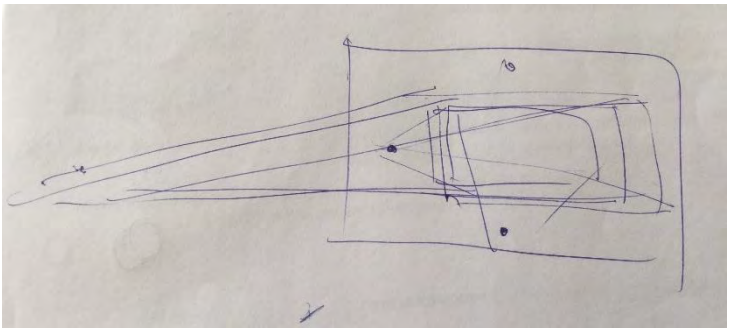


A lightmap also needs to be put inside the bore of the scanner. It can be done using a lightmap where there is not a light source but the objects are reacting as if they are receiving a certain amount of light. Alternatively, several small lights can be placed aligned within the device replicating what is there physically (several LEDs).

4. Certain objects in the room needs to have a reflection property added. To make it look like a glass that a person is standing behind reflection and refraction properties are needed. They are properties in the material library. Reflection is how much of the light is bouncing back off the object and refraction is how much of the light is going through it. A good way of doing this is to put the image of the person behind the wall.



Looking from the side view, the full thickness of the wall, there is some detail. After that have a glass which is a 5mm prism, this glass will have a refraction and a reflection property to it. Place the picture behind it and preferably have a large picture and place it right behind. For example, if it is right behind the glass, no matter how close or far away you look at it, you will always see the same thing. On the other hand, if a very large picture is put one metre behind, more is seen of it, but going further limits the view, shrinking the amount visible. This is the trick of making it realistic. When very close to the glass, 10cm more detail can be seen on the sides, top and the bottom. If there is a significant distance between, (say 1 metre) it gives the desired effect. Taking the size of the room, if the window is 2 metres, then take half of that. Looking at the window, you can see the thickness of the frames, and all the metals, in the real world edges can never touch each other. When it is modelled all the lines are perfect, they snap, but when it is rendered, the detail in between is lost and imperfections are created. Everything should be imperfect as it is this along with the light which will create the realism.



Create two versions, one with the figure on the bed and one without to show the MRI lead. When aiming for realism, if it can't be done perfectly, then it is better to leave it off. Free software is available for creating people. The software already has the people available and allows each of the joints to be controlled. So take one of these models, create a relaxed looking guy from an average looking person model and export that. Assign him 0% reflection, (this means it will look like a silhouette when it is dark), a dark material, a very high transparency in terms of the material and then he will look like the shadow of the guy. It will not be the same as a 2D silhouette because when the user moves their head it will look realistic in terms of where it's body proportions are. When the camera is moved forward, it won't stay still, giving the real silhouette of a real existing guy. Otherwise a PNG image of a transparent guy can be used, but it would not look the same.

Regarding the control room, a real picture of the room is required. Take a picture of the glass with someone behind it and place it one metre behind the glass. No animation is needed. Make the guy look dark enough (in Photoshop) so that his details are less visible. He should be in an idle position. If he is standing in an idle, observing position, then people will not question that he is not moving. In Photoshop you can add blur, if the details are not sharp, people will not see it at all.

5. Do not use texture - work with the bump map to make it more realistic. The MRI model is rendered in one colour. Recolour different portions because if it has differences between its components, it looks more realistic when the light shines on it, otherwise it will look like it has not been painted. Bump map is an image which can be found on the internet easily. Work with the bump map and diffuse, this means the basic colour of the object and it also has the properties like how transparent it is.

Anything that is viewed from far away, cannot determine whether a bump map is used or not. It is only needed on the inside of the bore. Using a bump map has the effect of turning a picture of the MRI scanner to feel like the real version of it. The same can be done for an outside window.

With the resulting application now available, work focused on the other deliverables required to take the prototype into the lab. These were movement restriction and measurement of anxiety.

C.1.2 Movement restriction

A prototype helmet was made courtesy of he mechanical engineers at the hospital as shown in figure C.1.

Figure C.1: Ear muffs and first prototype head brace - P1 made by medical engineers from a white plastic bucket with restraint strap

C.1.3 Measurement of anxiety via skin conductance sensors

Hospital engineers were also engaged to advise on creating a skin conductance sensor but this proved unsuccessful and sensors from a commercial relaxation package (Wild Divine) were tested out to see if they would be effective in the MRI room. These were Wild Divine IOM sensors model No. as in figure C.2.

Figure C.2: Wild Divine IOM sensor model no

C.2 Equipment Detail

C.2.1 Assessed

The equipment assessed has been included in Appendix D. Those items used in the experiment are given below.

C.3 Consideration of Data Harvesting Platforms

C.3.1 Pricing Quotes Summary Table

Options for measuring electrodermal activity (EDA) in an MRI environment

Recording skin conductance data during an MRI scan poses the problem that no ferrous metal is allowed inside the MRI room. The Wild Divine IOM device currently being used needs to remain at least 2 metres from the bore of the scanner. A solution has been to put the sensors on participants' toes. However during pilot testing it has been found people's toes differ in shape and size. Sometimes it is not possible to put the sensor over the toe or attach it in a way that gives constant skin contact. Thick skin also is problematic. A better solution would be to attach the sensors to the in-step or palmer sites of the foot or hand requiring a different design of sensor. Few companies compete in this space. I propose this could be a shared investment for the HITLabNZ.

Ref	OPTION	Product	SCL (EDA)	HRV	MRI ok		Delivery time	
1	Wild Divine	IOM Device	Y	Y	N	Data collection very sporadic. Analysis all manual. Ideally require a reading at 1-3 per second.		$179 purchased
2	BIOPAC Call +1 805 685 0066	MP150 EDA100C-MRI MEMRI-TRANS 2xLEAD 108B EL509 + GEL101 (+ Shipping) (ECG100C-MRI)	Y	(Y)	Y	I would consider this solution the most suitable. It would enable data gathering in sync with the MRI scanner and data analysis to be carried out with automated options. The MP150 supports up to 16 channels of physiological data. A pricing option is available which includes six types of input. This would be suitable for general lab use. BIOPAC is used elsewhere at UC. $548.92 has been quoted for shipping to NZ. Plus cost of MP150 and cables. (Note: price for non MRI ECG is half = $774.00)		6654.00 1554.00 1434.00 156.00 210.00 +175.00 **10,183.00** 3104.00
3	iMotions Empathica/iMotions	Shimmer Wristband	Y Y	 Y	N N	GSR s/w + GSR h/w respectively Comparable emotions platform (s/w). Sensors also work with BIOPAC MP150. Unable to be used in the MRI.	2 weeks to ship	3350.00 990.00 2900.00 **7150.00**
4	MIND	Mind Input device	Y		Y	Unable to determine how to purchase.		
5	Build Your Own	Fibre optic cables and disposable sensors	Y	Y	Y	Need more detailed plan to build from plus testing time. Current SCL sensors developed in the Lab are not MRI friendly.		

Note: prices are assumed to be in US dollars, ? = price and delivery time requested

C.4 Input Data Files

Demographic data was coded as detailed in table C.4.

Description	Meaning	Original Value	Coded Value
Group	Experimental	E	1
Group	Control	C	0
Experience	Virtual Reality and MRI	VR	1
Experience	MRI only	MRI	1
Gender	Male	M	1
Gender	Female	F	2
Ethnicity	NZ European	NZEuropean	1
Ethnicity	English	English	2
Ethnicity	Ukranian	Ukranian	3
Ethnicity	Other	Other	4
History of anxiety	Yes	Y	1
History of anxiety	No	N	0
Own MRI history	Has had a previous MRI scan	Y	1
Own MRI history	Has had a previous MRI scan	N	0
Others' MRI	Has heard of others' MRI scan	Y	1
Others' MRI	Has heard of others' MRI scan	N	0

Figure C.3: Coding translation table

Patient Participant Input files – titles and their values

Description	Meaning	Value
Age	Year range 18-24	1
Age	Year range 25-34	2
Age	Year range 35-44	3
Age	Year range 45-54	4
Age	Year range 55-64	5
Age	Year range 65-74	6
Age	Year range 75-84	7
Age	Year range 85-94	8

Description		**Meaning**	**Value**	**Format/ position**	**Example**
Title of anxiety measure		Key identifier of the measurement (with participant id).		xxxxxx	VHRA
Title of anxiety measure	Group	Value from the Virtual Reality scan simulation	V	1	
Title of anxiety measure	Group	Value from real MRI scan	M	1	
Title of anxiety measure	Measure	General Anxiety Scale	GAS	2	
Title of anxiety measure	Measure	State Trait Anxiety Inventory	STAI	2	
Title of anxiety measure	Measure	Skin Conductance Level	SCL	2	
Title of anxiety measure	Measure	Heart Rate	HR	2	
Title of anxiety measure	Measure	Blood Pressure Systolic	BPS	2	
Title of anxiety measure	Measure	Blood Pressure Diastolic	BPD	2	
Title of anxiety measure	Treatment	Before	B	3	
Title of anxiety measure	Treatment	During	D	3	
Title of anxiety measure	Treatment	After	A	3	

Description	**Question**	**Meaning**	**Value**
VRvsReal	During the time of the experience, which is the strongest on the whole, your sense of being in the virtual scan, or of being in the real scan?	Sliding Likert scale value (1-4) where 1 is 'Being in the Real scan' and 4 is 'Being in the virtual scan'.	1,2,3,4 blank
OvbyVR	To what extent were there times during the VR experience, did you often think to yourself that you were actually just laying on a bed wearing a helmet or did virtual reality overwhelm you?	Sliding Likert scale value (1-4) where 1 is 'VR overwhelmed me' and 4 is 'Just wearing a helmet'.	1,2,3,4 blank
MVRisReal	How did your anxiety level from the VR experience reflect the real MRI experience?	Specific Likert scale value where '1=not at all', 2=somewhat, 3=moderately and 4=very much'.	1,2,3,4 blank

Appendix D

Usability Detail

D.1 Lab Pilot Detail

Items subsequently discarded have been marked with an asterisk (*).

D.1.1 Lab Equipment

- Black three-seater couch * (to simulate bed)
- Prototype 1 Head Brace * (white bucket from Hospital Engineers with restraining strap)
- Disposable paper towel
- Anti-bacterial wipes
- chair

D.1.2 Lab Hardware

VR APPLICATION

- Head Mounted Display - Samsung gear VR
- Mobile phone - Samsung Galaxy S6 edge+
- Medical Ear Muffs - Ear defenders supplied by Hospital *
- Laptop or PC - for running screen sharing *
- Power cord
- 5-socket power extension with pulse protection

  AUDIO RECORDING
- Device to record audibly - iPad

  SCREEN SHARING
- Wi-Fi Access Point (modem/router) or extra mobile phone *

- ethernet cable * (or use Wi-Fi as an alternative)
- 1 power cord *

  PHYSIOLOGICAL SENSOR
- 2 GSR Sensors - Wild Divine IOM White Sensors *
- Heart rate sensor - included in the above
- USB RF shielded 5 metre or longer extension cable

D.1.3 Lab Software

VR APPLICATION

- VR Experience Application in Unity built for Android AUDIO RECORDING
- Audio recording software - Audio note for iPad * SCREEN SHARING
- Wi-Fi Hotspot ability - Laptop PC computer running Windows
- Windows 8 (Windows 10 not compatible) *
- Samsung SideSync installed on phone and on PC *
- QR code scanner installed on phone * PHYSIOLOGICAL SENSORS
- Sensor Device Maintenance - Wild Divine IOM Driver
- Sensor Interpretation software - Wild Divine IOM Grapher

D.1.4 Lab Pilot Suggestions for Improvement

LAB RESEARCHER'S SCRIPT

Deliver small chunks of content. Use the term, 'something to brace your head'. Add 'Your head will be restricted.'

LAB QUESTIONNAIRE

Enlarge font on questionnaire for ease to reading. Small text could cause anxiety dependent on User group. Complete the 'After' questionnaire just before participant departs. Read out the 'during' questions while still on the bed with headset and headphones on. "On a scale from 1 to 4, 1 being 'not at all'; 2 being 'somewhat'; 3 being 'moderately' and 4 being 'very much' how would you rate this statement? "I feel calm". Again, 1 is 'not at all'; 2 is 'somewhat'; 3 is 'moderately' and 4 is 'very much'? The next question is "On the same scale, "I am tense"; not at all, somewhat, moderately, very much. Remove superfluous text. New versions have included in this document as an appendix.

LAB CONSENT FORMS

Provide a clipboard. New versions of forms have been included in this document as an appendix. Changes are to replace check-boxes with only one. Replace postcode with town. Neutralise

statements with Y/N. Remove “If any of the above conditions are noted, details are recorded and the participant excluded from the study” It is the action for researcher to know, not participant. Remove “Please inform the medical staff .... “ Replace with neutral statement Y/N.

LAB VR APPLICATION

Explain the mirror, tell them you are going to be put in this. “We are going to simulate..”. While the head brace was being put on, there was no immersive equivalent in the VR. Include something in the VR simulation or just omit using it altogether. If something is added to the VR component, putting head phones would function sufficiently. With or without glasses, breath creates fog on lenses of VR headset when using prototype 1. Revise prototype.Users did not realise that the whole body needs to be rotated towards the control room. There is currently a disconnect between physical and virtual body, with only the head being tracked. Change text to be more specific or remove ambiguity. Look => face (with your body). Ensure researcher can see what the participant can see. Turn down the noise / alternatively the scanner noise in the simulation needs to be much louder like a pounding bang! Bang! Bang! to replicate the MRI procedure. Replace ill fitting earmuffs with good quality noise cancelling headphones to clarify sounds from the headset, not muffle them. .

D.1.5 Lab Pilot Issues for Correction

- Explanation of risks to those taking part and how will these be managed.
- Enable screen sharing between phone and laptop.
- Science is used for prediction and reproducibility. Any form of science needs these two things. (This is what we did, this is the results we got and this is HOW we got there. The bucket (head brace prototype 1) introduces too much variability into the study and has been replaced by the alternative prototype as a result of iterative design.
- What constitutes is an acceptable level of prediction? This needs to be established first. Then, how will this be completed? Research Data processes need to be thoroughly worked through so that the method of analysing results is defined and verified before taking into the Hospital for further data collection. One example, how is the data from the STAI Y-6 questionnaire to be analysed? Another is how skin conductance data from the galvanic skin response sensors will be analysed?
- Data gathered from skin sensors has been sporadic. It has been concluded that the case for change will be stronger if medical staff come to the conclusion that something else is needed. They are likely to take longer to reach that point but it should prove more beneficial overall.
- Process Steps Initially, manual transcription of STAI Y-6 questionnaire responses onto spreadsheet. There are better ways for data collection which reduce the risk of introducing human error, however given the available resource, it was decided that a paper copy would be the option used used as most patients would be familiar with pen and paper.

D.2 Hospital Staff Pilot Detail

D.2.1 Hospital Equipment

- Medical Trolley bed with sheet

- Prototype 2 head brace with pillow and breath plate for HMD– towel for head brace
- Prototype 3 head brace with pillow and cardboard visor
- Prototype 4 head brace with pillow and perspex visor
- Disposable paper towel
- Anti-bacterial wipes
- Trolley to hold hardware
- chair

D.2.2 Staff Pilot Hardware

Items later discarded have been annotated with an asterisk (*).

VR APPLICATION

- Alternative Head Mounted Display - Oculus DKII *
- Laptop running Oculus DKII *
- Power cord
- Head Mounted Display - Samsung gear VR
- Mobile phone - Samsung Galaxy S6 edge+
- 5-socket power extension with pulse protection

AUDIO RECORDING

- Bose Noise cancelling headphones*
- Non-noise cancelling headphones
- Zoom H4n portable recorder
- power cord *

VIBRATION

- Buttkicker Concert (240v)
- Pre-Amplifier
- Amplifier
- Speaker leads between buttkicker and pre-amp

- Audio lead (red and white plugs) between pre-amp and amp
- Audio lead (red and white plugs from amp to audio connector
- Audio connector to audio splitter
- Audio splitter feeds into HMD audio output jack.
- Audi power cords (1 or 2)

  PHYSIOLOGICAL SENSOR

- 2 GSR Sensors - Wild Divine IOM White Sensors *
- Heart rate sensor - included in the above *
- Reconciliation Sensor - Hospital's own MRI friendly Heart rate Display sensor
- Alternative instep option: 2 GSR Sensors - Wild Divine IOM Blue flat sensors with pad
- Foot cradle to house pad *
- Heart rate sensor - included in the above*
- USB RF shielded 5 metre or longer extension cable

D.2.3 Staff Pilot Software

VR APPLICATION

- VR Experience Application in Unity built for Android

  AUDIO RECORDING

- Steinberg Cubase LE

  SCREEN SHARING

- Wi-Fi hotspot ability - Laptop PC computer running Windows 8 (Windows 10 not compatible)*
- Samsung SideSync installed on phone and on PC *
- QR code scanner installed on phone *

  VIBRATION

- None

  PHYSIOLOGICAL SENSORS

- Sensor Device Maintenance - Wild Divine IOM Driver
- Sensor Interpretation software - Wild Divine IOM Grapher

The IOM device was set running on the PC by right clicking 'show device status'

D.2.4 Equipment Set-up

This setup was used to enable screen sharing. It was withdrawn early in the pilot stage due to complexity of setup (introducing too many variables) and practicality of running within the experiment in the constrained time period.

- Create a wireless access point to enable non wired communication between the phone (in the headset) and the laptop. The most reliable way of doing this is to use a modem with Ethernet port plugged into the laptop PC. From the router, only a power lead is required.
- Sign onto Wi-Fi network on the PC.
- Sign onto the same Wi-Fi link on the phone.
- Open Samsung SideSync application on the PC.
- Open SideSync on the phone.
- Connect the phone by scanning the QR code displayed on the PC, with the phone.
- Select ‘phone screen icon’ on the PC’s SideSync pop-up window.
- Click on ‘presentation mode’ (top left of emulated phone screen window) to enable on PC.
- Check media volume setting on the phone. Turn to maximum (ignore warning). The ring tone should be set to minimum.
- Plug in audio headphones and turn noise cancelling switch to ‘on’.
- Select VR application on phone.
- Insert connection into phone in headset and click shut.
- It should come up with ‘Unity’. If ‘Oculus Store’ appears something else has been triggered. Repeat the previous step.
- Now the application should be visible on the PC window.

D.3 Hospital Patient Pilot Detail

D.3.1 Patient Pilot Experiment Setup

EQUIPMENT

- Medical trolley bed with sheet
- Prototype 4 head brace with pillow
- Blue cotton pillowcase
- White cotton sheet

- Anti-bacterial wipes
- Trolley to hold hardware
- chair
- Over the bed table

D.3.2 Patient Pilot Hardware

VR APPLICATION

- Head Mounted Display - Samsung gear VR *
- Mobile phone - Samsung Galaxy S6 edge+ *
- Headphones - Sennheiser without noise cancelling
- Disposable Headphone covers for headphones
- Headphone cable connects via audio splitter into HMD.
- laptop or PC - for running screen sharing
- power cord
- 5-socket power extension with pulse protection

  AUDIO RECORDING

- Camera with tripod to record audio and visual response from the Grapher software - Panasonic HC-WXF990M

  SCREEN SHARING
  Screen sharing has been removed from the study.

  VIBRATION

- Buttkicker Concert (240v)
- Pre-Ampliflier
- Amplifier
- Speaker leads between buttkicker and pre-amp
- Audio lead (red and white plugs) between pre-amp and amp
- Audio lead (red and white plugs from amp to audio connector
- Audio connector to audio splitter
- Audio splitter feeds into HMD audio output jack.

– Audi power cords (1 or 2)

PHYSIOLOGICAL SENSOR

– 2 GSR Sensors - Wild Divine Blue Sensors modified to enable record of skin response on the muscle under the instep of the foot

– heart rate sensor - included in the above

– USB RF shielded 5 metre or longer extension cable

– Reconciliation Sensor - Hospital's own MRI friendly Heart rate Display sensor

D.3.3 Patient Pilot Software

VR APPLICATION
No change Audio Recording

– video and audio provided by camera

VIBRATION
No change

– D.3.4 Physiological sensors

SENSOR SOFTWARE Installed on MRI control room PC (Windows)

– Sensor Device Maintenance - Wild Divine IOM Driver

– Sensor Interpretation software - Wild Divine IOM Grapher

Appendix E

Experimental Method Detail

E.1 Day-to-Day Procedure

On arrival, I worked through the daily set-up sheet to ensure all equipment was set up correctly for the day.

E.1.1 Experimental Group: Daily Set-up

For each experimental participant, the daily setup sheet was checked to ensure all items were addressed ideally before the next patient's arrival. The daily set up is not required for control participants.

Daily Set-up

Connect butt-kicker, turn on pre-amp and then amp. Check audio calibration. Plug in sensors with extension, iom device and grapher. Set up and focus camera. Create today's data folder. Confirm participants and mark up forms.

For each participant

1 Turn on amp ☐

2 Phone – check Bluetooth on. Pair with Logitech keyboard ☐

3 Check media volume setting on the phone. Turn to maximum (ignore warning). Ensure ringtone is at minimum. ☐

4 Ensure headphones are plugged into splitter ☐

5 Connect lead from splitter into headset ☐

6 Select VR application on phone. ☐

7 Insert connection into phone in headset and click shut. ☐

8 It should come up with 'Unity'. ☐
If 'Gear VR update or Oculus Store appears something else has been triggered. Take phone out, choose VR app and re-insert.

9 Put on headset and turn volume on keyboard up to max. ☐

10 Press volume down on key board twice. (should be hearing 'chirp') ☐

11 IOM device status and grapher ready? ☐

12 Check BP monitor ready ☐

Call participant

E.1.2 Data Gathering: Common Forms

Forms common for both experimental and control groups are:

- Demographics Form
- Physiological Measurements (before and after)
- Researcher Script for MRI

Researcher Script for MRI

Participant Id:____ Date: / /2016 Start time: _____

From MRI VR cubicle.

If participant has been assigned to control "Good afternoon/morning _____. My name is Helen. "Here are the consent forms I collected earlier. Please confirm this is you. ☐

"Here is an information sheet. For in-patients: "You may recall seeing it before up on the ward. You are welcome to keep it." ☐

Thank you for agreeing to be involved in this research. Do you have any questions for me? ☐

"I will be taking some measurements before and after your scan."
Capture on camera/iPad using hospital BP monitor
This will measure your blood pressure and heart rate. ☐
Take blood pressure and note both this _____ _____ ___
and heart rate_____bpm
I shall be using these sensors on your left hand to measure your skin conductance (which is how much you perspire). ☐
Take measures and read off camera/iPad SCL _____ siemens ☐

I shall be using disposable covers and wiping equipment with antibacterial wipes to ensure all the things we are using are cleaned before we start." ☐

"I shall be measuring your emotional state by asking you to complete a questionnaire three times. "Here is the first, just before we start" ☐

Give STAI to participant to complete. "Would you prefer me to read it and
☐ complete or do it yourself? *On a scale of 1 – 4 where 1 is not at all.."* ☐

"Thank you" *Check all answers have been completed* ☐

"Are you ready to begin?

The patient will enter the scan room for their MRI scan.
On coming out
"I'll take your 'after' measurements now. *Capture on camera/iPad*

So, this will measure your blood pressure and heart rate again." □

Take blood pressure and note both this _____ _____ ___
and heart rate_____bpm

I shall be using these sensors again on your left hand to measure your skin conductance (which is how much you perspire).

Take measures and read off camera/iPad SCL _____ microS □

Offer to the patient to read and complete (or read out the STAI questionnaire and record scoring). □

Are there any remarks you would like to leave behind before we finish this session? □

Thank you so much for taking part." □

Data being recorded for _____ Date …/ /2016 End Time: _____

Participant Questionnaires were separate for experimental and control patients.

E.1.3 Data Gathering: Experimental Group

Researcher Script for VR

Researcher Script for VR

Participant Id:____ Date: / /2016 Start time: _____

In the MRI VR cubicle...

Thank you for agreeing to be involved in this research. Do you have any questions for me? ☐

If patient is able to get onto the bed unaided "Please sit comfortably on the bed. "
Else get staff assistance to maneuovre patient onto the study bed ☐
"I will be taking some measurements before and after your scan."

Capture on camera/iPad
This will measure your blood pressure and heart rate. ☐
Take blood pressure and note both this _____ _____ ___
*and heart rate*_____*bpm*

I shall be using these sensors on your left hand to measure your skin conductance (which is how much you perspire). ☐
Take measures and read off camera/iPad SCL _____ siemens ☐

I shall be using disposable covers and wiping equipment with antibacterial wipes to ensure all the things we are using are cleaned before we start. ☐

"I shall be measuring your emotional state during the VR simulation by asking you to complete a questionnaire three times. This will be completed for the MRI scan too. "Here is the first, just before we start" ☐

Give STAI to participant to complete. "Would you prefer me to read it and complete or do it yourself? *On a scale of 1 – 4 where 1 is not at all.."* ☐

"Thank you" *Check all answers have been completed* ☐

"Please make yourself comfortable on the bed with your feet in front of you."☐

I shall be giving you a VR headset for this experiment and placing ☐
ear muffs on your head. These are for helping with the noise from the scanner. I will also use something to recreate the feeling of the neck brace, which restricts movement and fits over your head. This equipment replicates what you will be given when you have your MRI scan. Please stay still as movement can spoil the pictures that are being taken by the scanner*".* You may stop at any time. If you wish to stop just tell me or squeeze this buzzer".
Give the participant a buzzer ☐

"Are you comfortable? Ready to begin*?"* ☐

"I will be able to hear you. You may not be able to hear me, so please let me ☐
RAISE YOUR HAND to know when you have come out of the scanner."

*Clean the headphones. "*These are the headphones I will be using." They will be put on first.

Clean the VR headset. "This is the VR headset. As I put it over your head you will see only what is on the screen in front of you. There is a dial at the top ☐
which you can adjust to improve the focus."

"You may look around. Opposite the scanner is a room where the MRI staff stand while taking your scan pictures. You will hear the voice of the MRI tech guiding you through. I will put on ear muffs and the neck brace. I am able to hear you. You are unlikely to hear me. " ☐

Let's put the headphones on first. This holds the headset firm. Please remove any earrings for your comfort. Would you like me to put these over your ears or would you prefer to do it yourself? *As requested* ☐

And the headset. Would you like me to put it over your head or do it yourself? *As requested. "*Is that comfortable?" ☐

"Here is the dial. Just to check the set-up, could you please read what it says on the scanner" *SIEMENS*

"Are you ready to begin? Remember, just raise your hand if you want to stopat any time. ☐

PRESS SPACEBAR (This will start the MRI tech talking) ☐

…On hearing POWERFUL MAGNET

□

PRESS SPACEBAR (This will take the participant to seeing model on the bed) □
Press volume key DOWN twice. "Can you see your feet?"
On 'Yes' PRESS 'UP' ARROW □

"Are you ready to begin the experience?
On 'Yes' Press volume key UP twice □
Align the head brace up for lying down □

REMEMBER The participant is prompted by the audio to 'Please LIE DOWN' □
Gently lay them down - count slowly to 55 while fitting the head brace with pillow, right foam, left foam and then helmet (over headset), left side, right side pushing down just an inch to ensure secure. □

ON COMPLETION Turn off the amp, press volume down on keyboard until quiet. □

Read out the STAI questionnaire sheet and record scoring □

PRESS SPACEBAR AGAIN Count to 5, remove helmet, guiding the participant to sit up, removing headphones, headset and finally sensors. □

"So now it is time to take the 'after' measurements."
Capture on camera/iPad
First your blood pressure and heart rate. □
Take blood pressure and note both this _____ _____ ___
*and heart rate*_____*bpm*

"Then the skin conductance again". □
Take measures and read off camera/iPad SCL _____ siemens □

Depending on patient mobility give them the results to complete or talk through it and complete on the participant's behalf.

"Thank you. That's completed the VR part. Now onto your scan".

Participant Id: ___ Date/Time: _____ Stage: VR / Before

A number of statements which people have used to describe themselves are given below. Read each statement and then mark the most appropriate number to the right of the statement to indicate HOW YOU FEEL RIGHT NOW, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	Not at all	Somewhat	Moderately	Very Much
1. I feel calm	1	2	3	4
2. I am tense	1	2	3	4
3. I feel upset	1	2	3	4
4. I am relaxed	1	2	3	4
5. I feel content	1	2	3	4
6. I am worried	1	2	3	4

Please make sure that you have answered **all** the questions

7. Give your highest anxiety level right now

Where 1=not at all anxious

1	2	3	4

Participant Id: ____ Date/Time: _____ Stage: VR / During

Read each statement and then mark the most appropriate number to the right of the statement to indicate how you FELT DURING YOUR VR SCAN.

	Not at all	Somewhat	Moderately	Very Much
1. I feel calm	1	2	3	4
2. I am tense	1	2	3	4
3. I feel upset	1	2	3	4
4. I am relaxed	1	2	3	4
5. I feel content	1	2	3	4
6. I am worried	1	2	3	4

Please make sure that you have answered **all** the questions

7. Give your highest anxiety level DURING your VR scan.
   Where 1=not at all anxious

1	2	3	4

Participant Id: ____ Date/Time: _____ Stage: VR / After

A number of statements which people have used to describe themselves are given below. Read each statement and then mark the most appropriate number to the right of the statement to indicate HOW YOU FEEL RIGHT NOW, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	Not at all	Somewhat	Moderately	Very Much
1. I feel calm	1	2	3	4
2. I am tense	1	2	3	4
3. I feel upset	1	2	3	4
4. I am relaxed	1	2	3	4
5. I feel content	1	2	3	4
6. I am worried	1	2	3	4

Please make sure that you have answered **all** the questions

7. Give your highest anxiety level right now.

Where 1=not at all anxious

1	2	3	4

Finally:

During the time of the experience, which was strongest on the whole, your sense of being in the virtual scan, or of being in the real scan?

Being in the REAL scan …… Being in the VIRTUAL scan

1 2 3 4

To what extent were there times during the VR experience, did you often think to yourself that you were actually just laying on a bed wearing a helmet or did virtual reality overwhelm you?

VR Overwhelmed me ……Just wearing a helmet

1 2 3 4

Are there any remarks you would like to leave behind before we finish this session?

Many thanks for your time and comments.

Participant Id: ___ Date/Time: _____ Stage: VR/MRI / Before

A number of statements which people have used to describe themselves are given below. Read each statement and then mark the most appropriate number to the right of the statement to indicate HOW YOU FEEL RIGHT NOW, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	Not at all	Somewhat	Moderately	Very Much
1. I feel calm	1	2	3	4
2. I am tense	1	2	3	4
3. I feel upset	1	2	3	4
4. I am relaxed	1	2	3	4
5. I feel content	1	2	3	4
6. I am worried	1	2	3	4

Please make sure that you have answered **all** the questions

7. Give your highest anxiety level right now

Where 1=not at all anxious

1	2	3	4

Participant Id: ____ Date/Time: _____ Stage: VR/MRI / During

Read each statement and then mark the most appropriate number to the right of the statement to indicate how you FELT DURING YOUR MRI SCAN.

	Not at all	Somewhat	Moderately	Very Much
1. I feel calm	1	2	3	4
2. I am tense	1	2	3	4
3. I feel upset	1	2	3	4
4. I am relaxed	1	2	3	4
5. I feel content	1	2	3	4
6. I am worried	1	2	3	4

Please make sure that you have answered **all** the questions

7. Give your highest anxiety level DURING your MRI scan.
   Where 1=not at all anxious

1	2	3	4

Participant Id: ____ Date/Time: _____Stage: VR/ MRI / After

A number of statements which people have used to describe themselves are given below. Read each statement and then mark the most appropriate number to the right of the statement to indicate HOW YOU FEEL RIGHT NOW, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	Not at all	Somewhat	Moderately	Very Much
1. I feel calm	1	2	3	4
2. I am tense	1	2	3	4
3. I feel upset	1	2	3	4
4. I am relaxed	1	2	3	4
5. I feel content	1	2	3	4
6. I am worried	1	2	3	4

Please make sure that you have answered **all** the questions

7. Give your highest anxiety level right now.

Where 1=not at all anxious

1	2	3	4

Finally:

How did your anxiety level from the VR experience reflect the real MRI experience?

Not at all	Somewhat	Moderately	Very much
1	2	3	4

Are there any remarks you would like to leave behind before we finish this session?

Would you like a copy of your results? Yes No

(Please give email address to receive results)

Thank you so much for taking part in this research.

E.1.4 Data Gathering: Control Group

Participant Questionnaires

Participant Id: ___ Date/Time: _____ Stage: MRI / Before

A number of statements which people have used to describe themselves are given below. Read each statement and then mark the most appropriate number to the right of the statement to indicate HOW YOU FEEL RIGHT NOW, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	Not at all	Somewhat	Moderately	Very Much
1. I feel calm	1	2	3	4
2. I am tense	1	2	3	4
3. I feel upset	1	2	3	4
4. I am relaxed	1	2	3	4
5. I feel content	1	2	3	4
6. I am worried	1	2	3	4

Please make sure that you have answered **all** the questions

7. Give your highest anxiety level right now

Where 1=not at all anxious

1	2	3	4

Participant Id: ____ Date/Time: _____ Stage: MRI / During

Read each statement and then mark the most appropriate number to the right of the statement to indicate how you FELT DURING YOUR MRI SCAN.

	Not at all	Somewhat	Moderately	Very Much
1. I feel calm	1	2	3	4
2. I am tense	1	2	3	4
3. I feel upset	1	2	3	4
4. I am relaxed	1	2	3	4
5. I feel content	1	2	3	4
6. I am worried	1	2	3	4

Please make sure that you have answered **all** the questions

7. Give your highest anxiety level DURING your MRI scan.
Where 1=not at all anxious

1	2	3	4

Participant Id: ____ Date/Time: _____ Stage: MRI / After

A number of statements which people have used to describe themselves are given below. Read each statement and then mark the most appropriate number to the right of the statement to indicate HOW YOU FEEL RIGHT NOW, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	Not at all	Somewhat	Moderately	Very Much
1. I feel calm	1	2	3	4
2. I am tense	1	2	3	4
3. I feel upset	1	2	3	4
4. I am relaxed	1	2	3	4
5. I feel content	1	2	3	4
6. I am worried	1	2	3	4

Please make sure that you have answered **all** the questions

7. Give your highest anxiety level right now.

Where 1=not at all anxious

1	2	3	4

Finally:

Would you like to be offered a virtual simulation before your MRI scan?

Yes No

Are there any remarks you would like to leave behind before we finish this session?

Would you like a copy of your results?

(Please give email address to receive results)

Thank you so much for taking part in this research

E.2 Focused Weekend Procedure

E.2.1 Preparation

E.2.2 Invitation

E.2.3 Revised Researcher Script

E.2.4 Revised Participant Information

- Updated Information Sheet
- Updated Consent Forms

E.2.5 Revised Data Gathering

- Updated Demographics Form
- Updated Physiological Measurements

Preparation for Running Experiment Weekends

Progress Check – 26/8/2016 On 28thSeptember a progress check was taken. The experiment has been running since 26th August 2016 and to date, patient participant numbers have been slow to grow. Experimental group = 19 of which one was abandoned due to being unwell, another could not remember the VR simulation, and a further two were withdrawn from the study, so data was gathered successfully from 15 patient participants. Patient Ids: 2, 4. 6. 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28 (abandoned), 30, 32 (advised not suitable), 34(withdrawn by researcher), 36, 38 (researcher not present). At this current rate of 1 or 2 successful candidates per day, it was predicted that the experiment would take a further thirty days to complete. Control Group = 10. Patient Ids: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19. This co-incided with the business process changing as a second scanner has been installed into the hospital and will be ready to accept patients from 11th October. Before this point staff need to be trained and new working procedures introduced along with the construction work required to enable operation. Over this period current staff needed be training. Another approach was sought in addition to the current method. The decision to run both scanners over the weekend. Normal business would be taken by the new scanner and the current scanner manned for two dedicated weekends to enable this study. Approval was sought within the Hospital and granted for manpower to support an additional 50 MRI out-patient appointments. These patients will be numbers Control 20 onwards VR 40 onwards Send out invitation letters Fifty additional patients were selected from the waiting list, with the criteria of the population being people over 18, currently awaiting an MRI head scan procedure (referred by a specialist). Fifty appointment letters were produced and sent out inviting to attend over two weekends. Slots were scheduled where pratical every 30 minutes and a request to attend 30 minutes prior to their appointment to enable participation in this research. A flyer and the standard Information sheet with ethics approval were included in the mailout. See Appendix A and B for details

Weekend One

On the first weekend, two people assisted the principle researcher in processing the worklist.

The process took a while to settle in. Initially the MRI questionnaires were not completed and neither were the times taken. A suggestion to write down measurements in a separate sheet resulted in the individual sheets not being updated and hence introducing another risk of manual error. By de-briefing at

the end of the day, improvements were made and flow the following day was noticeable improved. All patients agreed to take part with the exception of one who the family concluded would not benefit from the simulation. Also, one gentleman participant id 27 withdrew from the control group after measurements were taken.

The numbers Sat 5 VR and 1 control Sun 8 VR and 1 control Positive feedback received: “The virtual test prepares you for the real test, so I feel the virtual test makes you calmer for the real test.” – Participant Id 46 “Could be useful for children to see how they will be”…..“children don’t hold back in the way adults do” – Participant Id 46. “If people were warned more about the sounds – or played loud horrible industrial house music, it might help. It helped having some idea of the experience before going in.” - Participant 54. “Cool – very good. It’s like a natural feeling that you are there.” The only time I was aware of wearing a helmet was when then the head brace was being packed tightly. “I found it absolutely marvellous – it was like a wee adventure” – VR Participant 56 “VR was great prep for MRI = No surprises. Great Experience”. “What you’ve got in there (VR) is about the same” – Participant Id 64 One frequent remark was how much stronger the vibrations in the simulation were to their MRI experience. This is dependent on what specific sequences medical diagnosis requires. The simulation was designed to introduce to one of the stronger calibration plans. There was one sequence in particular, not simulated, that the MRI technician said “really rocks the table”. In confirmation, one participant Id 58, remarked that their experience was of stronger vibrations in the MRI, noting “Very rocky” when asked how their MRI compared to the VR experience.

Negative feedback received: “The only thing that makes the VR thing feel real is the moving in… needs improvement of graphics like real-time video” – Participant 44. “VR didn’t make much difference” – Participant Id 62.